DOCTOR OF PHILOSOPHY

An investigation of the effectiveness of miniscrews in orthodontics

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An investigation of the effectiveness of miniscrews in orthodontics

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Declaration

I declare that the work presented in this thesis is all my own work, has not been previously accepted for a higher degree and I have consulted all references cited.

Fahad Alharbi

I confirm that the conditions of the relevant Ordinance and Regulations have been fulfilled.

Professor David Bearn (Supervisor)

Abstract

Aims

The aims of this study were to systematically review the evidence on miniscrews failure rate, their effectiveness in anchorage reinforcement, to assess the quality of reporting clinical trials in orthodontic literature in an observational study, to audit their use in the UK and to compare the anchorage effectiveness when measured against headgear and transpalatal arch in a randomised clinical trial.

Methods

In two systematic reviews, databases were searched, data was extracted, the risk of bias was assessed and meta-analyses were performed when appropriate. In the observational study, clinical trials reports that were published in four major journals from 2008-2012 were identified and assessed against CONSORT checklist to evaluate the quality of reporting. The audit was a prospective multi-centre audit investigating the use of miniscrews in the UK.
In a randomised clinical trial, orthodontic patients were randomly allocated into three groups (headgear, miniscrews or transpalatal arch). Digital models were measured to assess the anchorage loss.

Results

The first systematic review and meta-analysis demonstrated that the failure rate of miniscrews was 14.1%(95% CI, 12-16.5). The data were obtained from 43 studies (16 clinical trials and 27 cohort studies). The second systematic review showed that overall mean difference in molar movement was 2.206mm in favour of miniscrews (MD = - 2.20; 95% -1.21 to -3.19) when compared with conventional anchorage methods. The data were obtained from seven clinical trials.

The observational study assessed the reporting quality of 151 clinical trials and showed that clinical trials reports represented less than 5% of the articles published in four major journal and their reporting was suboptimal.

The audit showed that none of the agreed standards were met except for infection/inflammation around the screw resulting in loss or removal in 5.6% of the cases while the standards were being below 20%. The miniscrew failure rate in this audit was 24.2%. The total number of placed miniscrews was 1072.

The randomised clinical trial revealed no difference between headgear, transpalatal arch or miniscrews in regards to anchorage effectiveness. 51% of study models required to measure the primary outcome were missing.

Conclusion

- Based on the two systematic reviews, miniscrews have a modest failure rate and they are useful clinically to reinforce anchorage.
- Reporting clinical trials is suboptimal in orthodontic literature.
- The only item that met audit standards was failure due to infection /inflammation. The rest of the audit standards were not met. Recommendations are made to address these issues.
- In the clinical trial, no difference in anchorage effectiveness between headgear, transpalatal arch or miniscrews was found. The findings of this clinical trial should be interpreted with caution due to the missing data.

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Chapter 1. Introduction.

The term anchorage in orthodontics is defined as the control of unwanted tooth movement (Strang, 1941; Proffit, 2000; Feldmann and Bondemark, 2006). Anchorage management is considered a corner stone in orthodontic treatment planning. Good anchorage management is dependent on appropriate treatment planning, including extraction pattern, sequence of treatment and proper anchorage reinforcement method. For many orthodontists, headgear or transpalatal arch is considered the standard for anchorage reinforcement. Recent reports have claimed that the introduction of miniscrews provides a promising option for orthodontists to reinforce anchorage effectively with minimum patient compliance. A critical literature review about miniscrews shows that there are few randomised clinical studies investigating their clinical effectiveness in orthodontics (chapter 2, 3, 4). For this reason I have undertaken an investigation with the aim of exploring how many clinical trials have been done in the field of orthodontics, in general, and what is the quality of reporting of those clinical trials (chapter 5).

My principal research interest at this stage in my career is Miniscrews. Thus, I have investigated current use of miniscrews through a long-term national audit. In chapter 6 of this thesis, I present the results of the British Orthodontic Society national audit of miniscrews.

Finally, in an attempt to increase our understanding about miniscrews, I present the results of a multi-centre prospective randomised clinical trial (chapters 7-10). This clinical trial aimed to compare the anchorage effectiveness of classical anchorage reinforcement methods in orthodontics; headgear and transpalatal arch with the new anchorage reinforcement method; miniscrews. The factors that the comparison was based on were:

- Amount of mesial movement of the upper first molar
- Patients perception of each anchorage method

Chapter 2. Literature review.

2.1 Headgear

2.1.1 Historical Background

In the late nineteenth century, the pioneer orthodontists, Kingsley and Angle popularized the use of headgear in conjunction with fixed appliances in orthodontics. The use of headgear became less popular with the introduction of intraoral elastics. It was thought that headgear was an unnecessary difficulty for the patients, especially if class II and class III elastics could produce skeletal changes in addition to tooth movement. At that time it was believed that intraoral elastics could grow one jaw and restrain the other at the same time. However, the introduction of cephalometric radiography and analysis in 1940s did not support the claims about skeletal changes produced by intraoral elastics (Asbell, 1990; Jeon et al., 2006)

Cephalometric evaluation of intraoral elastic effects revealed adverse effects of retroclination of upper incisors and proclination of lower incisors (Oppenheim, 1936; Bien, 1951; Kanter, 1956; Reddy et al., 2000). As a result of these findings, headgear use became popular again. Findings of Kloehn (1947) about headgear effects in class II malocclusion returned headgear to the centre of orthodontic treatment philosophy.

In orthodontics, headgear has many possible clinical applications. Depending on the force magnitude and direction, headgear can produce varieties of tooth movement and/or change the skeletal relationship (Bowden, 1978a).

In this chapter, I will discuss the different uses of retraction headgear in orthodontics and, in particular, its use for anchorage reinforcement in the anteriorposterior direction for class II correction.

2.1.2 Components of retraction headgear

Retraction headgear to provide an extra-oral force compromises of a number of components.

Head and neck strap

This part of the appliance provides the extraoral source of the anchorage. It is either a headcap or a neck strap or a combination of them for retraction headgear (Figure 1).

Face bow

Retraction headgear is connected via the headgear face bow to either fixed, removable or functional appliances depending on the intended movement. The face bow comprises of an extra-oral bow which is soldered to an intra-oral attachment that is engaged in the headgear tubes. The inner part of the face bow is inserted to molar bands via headgear tubes if using fixed appliances to reinforce the anchorage or to distalise the upper molars. With removable appliances, tubes soldered to the molar clasps can be used to engage the face bow. Headgear tubes can also be added to a functional appliance through headgear flying tubes (Parkin et al., 2001a).

Another form of face bow is the J-hook which comprises of two curved wires attached to hooks soldered to the archwire to retract the canines or to intrude the upper incisors.

Safety mechanism

Several safety mechanisms were described in the literature to prevent injuries that can happen during headgear use. One of those mechanisms is designed to break away once an excessive force is used (Stafford et al., 1998). Other mechanisms are the safety characteristics of face bow with blunt ends, recurved reverse entry inner bows and locking mechanism such as Nitom (The Nitom Locking Face bow, Ortho Kinetics Corporation, Vista, Calif/GAC International Inc, and Central Islip, NY). In addition to these mechanisms, Masel (www.masel.com) safety strap (rigid neck strap), and locating elastics can be employed to make headgear use safer (Postlethwaite, 1989; Samuels et al., 2000).

The British Orthodontic Society (www.bos.org.uk) advises that two safety mechanisms at least from the ones mentioned above should be provided when headgear is used to prevent injuries from happening. In addition, written, and verbal instructions and clear demonstration on how to place the headgear and how to remove it should be given to the patients. Headgear should not be worn during contact sports, and patients should stop wearing the headgear if it is disengaged during sleep. If an injury happens from headgear, the patient should be seen in accident and emergency department soon after the injury occurring. Lastly, patients should be instructed to bring their headgear to each appointment and report any problems to their orthodontist (BOS, 2013).

Figure 1 a) Straight/combination pull, b) High-pull and c) Low-pull retraction headgear (Reproduced from Dental update (ISSN 0305-5000) with permission from George Warman Publications (UK) Ltd)

2.1.3 Headgear Indications

There are several uses for headgear in orthodontics including molar distalisation, labial segment retraction, asymmetric tooth movement, growth modification and anchorage reinforcement. I will describe these uses briefly.

Molar distalisation

Retraction headgear can distalise molars to correct class II molar relationships. The amount of distalisation achieved by headgear ranges from 0.14 mm to 6.6 mm as

reported in different studies (Table 1). Patients were asked to wear the headgear for 12-14 hours per day, and the applied force ranged between 400-500 grams.

Table 1 Studies invistigating headgear for molar distalisation

Authors	Study Design	Comparison group(s)	Sample size	Mean of Amount of distalisation in headgear (mm)
(Keeling et al., 1998)	RCT	1. Bionator 2. Headgear	325	2
(Bondemark and Karlsson, 2005)	RCT	1. Headgear 2. Intra-oral appliance with superelastic coils	40	1.7
(Efstratiadis et al., 2005)	RCT	1. Headgear 2. Regulator	65	1.8
(Altug et al., 2005)	RCT	1. Asymmetric headgear/Removable plate 2. Headgear/ Removable plate	20	6.6 in both groups
(de Oliveira Jr et al., 2007)	RCT	1. Jasper Jumper 2. Control 3. Headgear	75	0.14
(Acar et al., 2010)	RCT	1. Pendulum 2. Cervical pull headgear	30	0.8
(Toy and Enacar, 2011)	RCT	1. Pendulum 2. Headgear	30	0.77

The focus in this review will be on the effectiveness of headgear on anchorage reinforcement for class II cases and not on molar distalisation, so further analysis of these trials will not be performed. However, it is worth pointing out that a recent Cochrane review in 2013 about distalising techniques suggested that intraoral appliances were more effective than headgear in distalising upper first molars. The authors pointed out that this amount of molar distalisation is counteracted by anchorage loss that is manifested as increased overjet. This anchorage loss did not occur with headgear when compared with intraoral distalising appliances in a small number of studies (Jambi et al., 2013). Jambi and her colleagues pointed out that the

findings should be interpreted with caution as there were only a few clinical trials and the quality of evidence was low.

Headgear can also be used to regain lost space resulting from early loss of primary teeth by uprighting upper first molars as shown by Kurol and Bjerklin (1984) in a prospective cohort study of forty six participants. In their study, the lost space was regained successfully in 70 % of the cases. Poor compliance was the main reason for failure in the remaining 30 % of the cases as reported by the authors.

Bowden (1978) suggested that headgear use can result in tipping and extruding movement of the molars depending on the force level and direction of the applied force as well as the duration of headgear wear.

Canine retraction/labial segment movement.

J-hook headgear can be used for upper anterior teeth intrusion, maxillary canine retraction or occasionally lower canine retraction (Perez et al., 1980; Deguchi et al., 2008). Headgear wear for 10 hours per day and force levels of 100-150g per side on average are required for canine retraction (Bowden, 1978b; Güray and Orhan, 1997). Deguchi et al. (2008) in a randomised clinical trial found that J-hook headgear causes more root resorption in comparison with miniscrews with less effectiveness in incisors intrusion. Due to the risk of ocular injuries and as labial segment retraction can be performed more easily by other methods, J-hook is no longer used.

Differential (asymmetric) tooth movement.

Asymmetrical headgear (AHG) can be used to achieve asymmetric movement of the molars (Holmes et al., 1989). There are several designs for AHG but the main principle of action is Castiglione's Theorem. This involves a longer outer bow to produce greater movement on one side due to the heavier force on that side. Other designs of AHG include the power-arm face bow, soldered-offset face-bow, swivel-offset face-bow and spring-attachment face-bow (Hershey et al., 1981; Brosh et al., 2005; Jacobson, 1979). One drawback of AHG is the tendency to produce a scissor bite on the side of the long arm and an increase in difficulty when fitting the appliance (Martina et al., 1988). 10 hours/day wear with force levels of 250-300g per side is necessary to achieve the required movement (Bowden, 1978; Brosh et al., 2005).

Growth modification/Orthopaedic effect

Theoretically, headgear can make changes on the skeletal relationship (Bowden, 1978a). The mode of action is restriction of the maxilla forward and downward growth and this would allow the mandible to 'catch up' during treatment (de Oliveira Jr et al., 2007; Freitas et al., 2008; Lima Filho et al., 2003). It is recommended that the headgear is worn for 12-14 hours and the applied force is on average 450 g per side. The headgear has a restrictive effect on anterior maxillary growth and development and this results in a reduction in maxillary anterior displacement as suggested by some studies (Poulton, 1967; Wieslander, 1974; Chaconas et al., 1976; Lima Filho et al., 2003)

High-pull headgear can be used combined with a functional appliance to treat class II malocclusion cases with increased vertical dimension for growing children (Parkin et al., 2001b). Patients should be instructed to wear the headgear for a period of 12-14 hours/day with a force level of 400-500g/side to produce skeletal effects besides the full time wear of functional appliance. However, the evidence for the effect of headgear on the vertical dimension is weak as suggested in a recent Cochrane review (Lentini-Oliveira et al., 2014).

Anchorage reinforcement

Conventionally, headgear is used for anchorage reinforcement during orthodontic treatment. Graber (1955) described retraction headgear as '*more satisfactory*' if compared with other devices for Class II division 1 malocclusion management. However, significant amount of patient compliance is required for headgear to reinforce anchorage effectively. Force level of 250-300 grams per side is required for at least 10 hours a day on average (Bowden, 1978).

2.2 Transpalatal arch (TPA).

Robert Goshgarian introduced the transpalatal arch (TPA) in 1974 (Goshgarian, 1974). The Goshgarian TPA is an intraoral appliance, generally designed to follow the contour of the palate, consisting of a 0.9 mm or higher gauge wire that connects the maxillary first molar bands with a central loop (Daskalogiannakis, 2000; Chiba et al., 2003; Goshgarian, 1974). The rationale behind the Goshgarian TPA is coupling the root surface of two maxillary molars one on each side. Goshgarian described his orthodontic palatal arch in the patent summary (US 3792529 A) as an invention used for rotation, extrusion, intrusion and torqueing the upper molars. Since its introductions in the 1970s, many studies have investigated the claims about uses of TPA (Zablocki et al., 2008). Although the TPA design originally developed by Goshgarian is commonly used, other designs are available like the quad-helix appliance, Wilson 3D lingual appliance, Burstone's precision lingual arch with hinge cap attachment, NiTi molar rotator, NiTi palatal expander and Zachrisson-type transpalatal bar. These different TPA designs will not be discussed here as the focus in this review is on Goshgarian TPA design.

Figure 2 Goshgarian transpalatal arch (Reproduced from Dental update (ISSN 0305-5000) with permission from George Warman Publications (UK) Ltd)

2.2.1 Overview of uses of TPA in orthodontics

The TPA can be used to derotate molars, to correct unilateral or bilateral posterior crossbite, to preserve arch width, to control upper molar eruption, and to distalise upper molars. In this review I will present an overview of these uses of the transpalatal arch. Figure 3 summarises different uses of TPA.

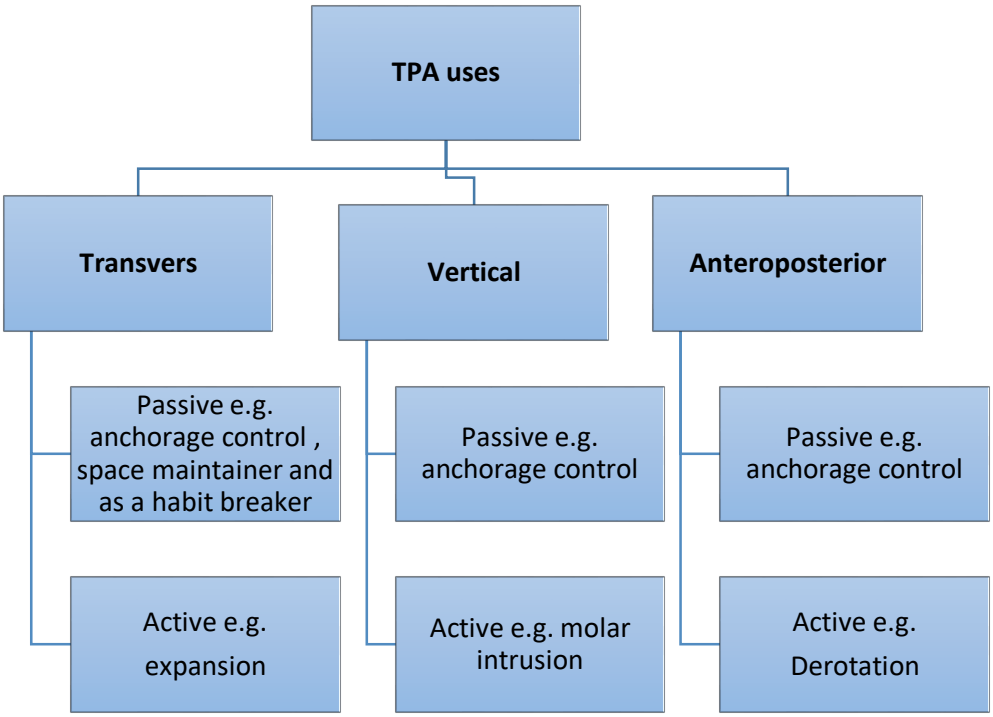


Figure 3 TPA uses (Reproduced from Dental update (ISSN 0305-5000) with permission from George Warman Publications (UK) Ltd)

Derotation

Rotated upper molars occupy increased space in the dental arch, and this may lead to class II molar relationship. The transpalatal arch is a convenient technique to produce equal and opposite moments to derotate rotated molars to gain space and improve the buccal segment relationship, especially if the derotation is necessary bilaterally (Ingervall et al., 1996). In a study that investigated the effectiveness of a TPA in the correction of symmetrical rotation of first upper molars, Dahlquist, Gebauer and Ingervall (1996) compared a control group (34 patients) who had normal occlusion with a group with a rotated upper first molar treated with TPA (50 patients) and found TPA is an effective technique in derotating a rotated upper molar (Dahlquist et al., 1996).

Other studies suggested modifications to the Goshgarian TPA design or material to perform asymmetrical or symmetrical derotation of rotated upper molars (Gündüz et al., 2003; Geramy and Etezadi, 2013). These were laboratory studies which tested different designs of TPA where they changed number or shape of the central loops. Geramy and Etezadi (2013) used 13 different design and tested them against each other using finite element analysis. They concluded the optimized model for correction of unilateral molar rotation was achieved by adding parallel straight wires to the palate (Figure 4).

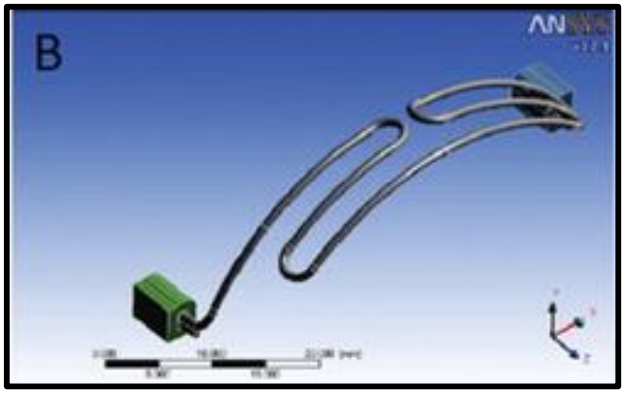


Figure 4 Parallel straight wire design (Geramy and Etezadi (2013)

Gunduz et al (2003) tested 10 Goshgarian type TPAs against 10 Zachrisson-type bars using a computer-based strain gauge. The Zachrisson type bar has three loops with the central loop larger than the central loop in the Goshgarian type. The findings of this study showed superiority of the Zachrisson design over the Goshgarian TPA for derotating molars.

Crossbite correction

In cases where the patient occludes in a crossbite posteriorly unilaterally or bilaterally, a TPA could be used to correct this problem. In a randomised clinical trial, Ingervall et al (1996) tested the effect of a Goshgarian-type TPA in 35 children with unilateral posterior crossbite. Fifteen of them received a TPA with an arch activated for expansion (expansion only) and the other group (20 patients) received Goshgarian-type TPA activated for expansion as the first group but with inclusion of buccal torque in the tooth that was not in crossbite (expansion and buccal torque in the anchor tooth). They found that in the first group (expansion only), both sides moved buccally while in the other group (expansion and buccal torque in the anchor tooth) there was significant movement of the molar in crossbite without significant

movement of the tooth on the other side (anchor tooth) (Ingervall et al., 1995). However, the Ingervall et al. trial had poor reporting quality without full presentation of randomisation.

Molar distalisation

An additional use of a TPA is in cases that require asymmetric distalisation of molars to correct a unilateral class II discrepancy. In clinical investigation by Eyuboglu et al (2014), 15 patients with class I molar relationship on one side and class II molar relationship on the other side were recruited. All participants received a Goshgarian-type TPA with 150 grams force to distalise the molar that was in class II relationship. They found the TPA effective in distalising the molars by 2 mm on average (SD= 0.704 mm) (Eyüboğlu et al., 2004).

Transverse expansion maintenance

The transpalatal arch can effectively aid in maintaining the transverse dimension of the maxilla after completion of a palatal expansion stage of the treatment. Alosie et al (2007) performed a randomised clinical trial where they performed surgically assisted maxilla expansion on 60 patients then randomly assigned them to one group with a retention period with a TPA (group 1) and another group without retention (group 2). In their assessment of interpremolar (A-A1) distance and intermolar distance (B-B1) on the dental casts at T1 (at the removal of expander) and at T2 (six months after the removal of the expander), they found no significant difference between T1 and T2 in A-A1 and B-B1 in the group assigned with TPA while there was significant difference between T1 and T2 in the group without retention with TPA (Aloise et al., 2007).

Space maintenance

Premature loss of primary molars can result in mesial drifting of the permanent molar and posterior crossbite. A TPA can be used in children with premature loss of the first primary molars as a space maintainer especially in cases of bilateral loss of maxillary second primary molars. Unfortunately, there are only a few studies investigating the effectiveness of TPA in space maintenance and case reports and

narrative reviews forming the only published reports (Laing et al., 2009, Kupietzky and Tal, 2007).

Vertical discrepancy correction

Increased anterior lower facial height can result from deficiency on the growth of the mandibular ramus, lack of vertical condylar growth, extrusion of buccal segment teeth or increase of alveolar growth (Ng et al., 2006; DeBerardinis et al., 2000; Alsafadi et al., 2016). Wise et al (1994) carried out a retrospective study on 40 patients, where a group of 20 patients received a transpalatal arch separated from the palate by 1-2 mm and a group of 20 patients did not receive a transpalatal arch, and tested the effectiveness of a transpalatal arch on vertical control of maxillary molars and found no statistical difference. They suggested that vertical dimension discrepancy could be corrected by using a modified design of the Goshgarian transpalatal arch through incorporating an acrylic pad to allow for tongue pressure and mastication forces to intrude the molars and prevent further vertical growth.

DeBeradinis et al (2000) tested this technique in a retrospective study where 16 patients were treated with Goshgarian transpalatal arch incorporating an acrylic pad combined with an 0.018-inch preadjusted edgewise appliance, and the other group were 16 patients treated with 0.022 inch standard edgewise brackets using the Tweed technique, including the use of high pull headgear. No significant difference was found between the two treatment groups. The authors suggested that a Goshgarian TPA incorporating an acrylic pad can be used to control vertical dimension. However, these findings should be interpreted with caution because the study was retrospective and the treatment protocols were not standardized. There is a lack of randomised clinical trials that assess the effectiveness of TPA for vertical dimension control.

2.2 Miniscrews

Miniscrews caught the imagination of orthodontists as a promising technology to provide several clinical applications. The concept of implants was introduced by Branemark, a Swedish researcher and his colleagues who pioneered the principle of osseointegration in restorative dentistry (Brånemark et al., 1969). Then, orthodontists tried to use stationary osseointegrated implants to provide anchorage during orthodontic treatment.

In 1960s, Linkow published a case report where he used a blade implant in the mandibular molar area for a bridge prior to orthodontic treatment in order to apply class II elastics to upper teeth and facilitate tooth movement (Linkow, 1969). Moreover, some orthodontists including Smalley and Blanco (1995), Kokich (1996), and Goodacre et al. (1997) suggested guidelines explaining how to use prosthodontic implants in order to provide orthodontic anchorage. Orthodontists even designed their own osseointegrated implants such as palatal implants and onplants which are different in diameter and length from restorative implants. However, all these osseointegrated implants require invasive surgical procedures which makes them less attractive despite providing "stationary" anchorage during orthodontic treatment.

The ideal implant for orthodontic purposes would be easy to place and remove, inexpensive, able to be placed in different anatomical sites in the jaws without damage to surrounding structures, biocompatible and able to withstand orthodontic forces (Cousley and Sandler, 2015). These features are not all found in osseointegrated implants and thus, alternative options were sought. In fact, Giansforth and Higley (1945) thought of alternatives to osseointegrated implants back in the 1940s but their experiment was not successful. They tried non-osseointegrated implants made of vitallium with 3.4 mm diameter and 13 mm long on five dogs and applied forces to retract upper canines using rubber bands. Unfortunately, none of the implants survived (Gainsforth and Higley, 1945). In a more successful attempt, Greekmore and Eklund (1983) placed a small non-osseointegrated vitallium bone screw above the anterior teeth of a patient with a deepbite to intrude the anterior teeth using elastics from the teeth to the implants. Despite the success of this attempt, it did not gain much attention at that time.

It was following Konami's (1997) publication that miniscrews as we know them today were popularized. Publications about miniscrews increased dramatically from few papers in the 1980s to almost 5000 papers up until 2015 indicating a huge interest in miniscrews (Cousley and Sandler, 2015). Unfortunately, the vast majority of these papers are case reports and biological science research and only a few clinical trials have been published.

I will focus again on the use of miniscrews for anchorage reinforcement anteroposteriorly using a systematic review approach. However, a brief description of other uses of miniscrews will be initially presented below.

2.3.1. Overview of uses of miniscrews in orthodontics.

Uses of miniscrews in orthodontics include molar distalisation, molar protraction, intrusion of incisors, intrusion of molars, crossbite or scissor bite correction and anchorage reinforcement. I will present an overview of these uses.

Molar Distalisation

TADs can be used effectively to distalise molars. Sugawara et al (2006) found that the amount of molar distalisation achieved was 3.78 mm (maximum 6.8 mm and minimum 1.5 mm) in a group of 25 patients. In this retrospective study, plates that were made of pure titanium and therefore, were suitable for osseointegration and tissue integration, were used for molar distalisation and then the amount of molar distalisation was measured on cephalometric radiographs (Sugawara et al., 2006). Molar distalisation of 3.27 mm on average were achieved by Cornelis and De Clerck (2007) in a prospective study of 17 patients with no control group. In this study, they used similar osseointegrated plates and they measured the amount of molar distalisation by superimposition of digitized models.

Yamada et al. (2009), in a retrospective study, found the amount of molar distalisation to be 2.8 mm on average (SD1.6mm) using non-osseointegrated mini screws inserted buccally between the second premolar and first permanent molar in 12 patients. In this study, cephalometric analysis of before and after treatment

radiographs was used to determine the amount of molar movement. There was a heterogeneity in the study sample as there were five patients with class II malocclusion, four patients with class I bimaxillary protrusion and three patients with class III malocclusion.

In a prospective study, Oberti et al (2009) achieved a mean distalisation of 5.9mm (SD1.7mm) in 16 patients using a bone borne distalising appliance supported by an acrylic button secured by two mini-implants. However, no control group was used and the measurements of the amount of molar distalisation were performed on cephalometric radiographs.

Tsui, Chua and Cheung (2012) performed a systematic review investigating the effectiveness of different systems of bone anchor (dental implants, miniscrews, palatal implants and miniplates) in orthodontic tooth movement. They found that the amount of molar distalisation that can be achieved by miniscrews is 3.9 mm on average (SD1.61mm). However, they concluded that there was limited evidence investigating the effectiveness of bone anchor systems in orthodontic treatment.

Molar protraction (Mesialisation)

Closing space posteriorly by molar protraction is difficult because of the need for anchorage reinforcement of anterior teeth. Anterior teeth have small combined root surface area in comparison to posterior teeth, thus providing less anchorage value during molar protraction. Miniscrews can be used to prevent the distal movement of anterior teeth during molar protraction. Unfortunately, most of the published reports about the effectiveness of miniscrews in molar protraction are case reports (Breuning, 2008; Jamilian and Showkatbakhsh, 2010), which are often biased by the author's experience or opinions and there is no control of confounding factors.

Intrusion

Miniscrews enable the orthodontist to intrude single or multiple teeth. Intrusion of anterior teeth using miniscrews can be used to correct deepbite. Deguchi et al (2008) analysed the effect of miniscrews on incisors in a group of eight patients and J-hook headgear in a group of ten patients. They found that miniscrews were more effective at incisor intrusion and cause less root resorption in comparison with J-hook

headgear. In this retrospective study, the difference between the two groups was statistically significant.

Senisik and Turkkahraman (2012) performed a RCT to investigate the intrusion efficiency of mini-implants in comparison with Connecticut intrusion arches. In this study, 45 patients with deep bite were divided into three groups: two treatment groups and one control group. The investigation period was seven months where no other treatment was executed with the exception of maxillary incisor intrusion. They found that in the mini-implant group the amount of incisors intrusion was 2.47mm (SD 0.81) and 2.20 mm (SD 0.9) in the Connecticut intrusion arches. Both treatment groups successfully intruded the maxillary incisors and the overbite significantly decreased compared to the control group. However, the difference between the two groups was not statistically significant.

Figure 5 Connecticut intrusion arch (Senisik and Turkkahraman, 2012)

Figure 6 Implant for intrusion (Senisik and Turkkahraman, 2012)

Recently, Jain, Kumar and Manjula (2014) published their RCT where they investigated the effectiveness of mini-implants, J-hook headgear and utility arch techniques in intruding maxillary incisors. 10 subjects were randomly allocated to each group. The amount of maxillary incisors intrusion was 2.1 mm (SD 0.21), 0.75mm (SD 1.2) and 1.33mm (SD 0.6) for mini-implant group, J-hook headgear and utility arch groups respectively (Jain et al., 2014).

Similarly, miniscrews can be used to intrude molars to correct anterior open bite. Park et al in 2004 suggested a combination of both maxillary and mandibular mini-implant anchorage to prevent molar tipping and tooth extrusion during the closure of premolar extraction spaces and then, in another study in 2006 , to intrude the molars directly to correct the anterior open bite. A small secondary counter-clockwise rotation of the mandible was also observed in these two case reports (Park et al., 2004; Park et al., 2006b).

Kuroda et al (2007) in a retrospective study compared the effectiveness of mini-implants in treating anterior open bites in comparison with LeFort I osteotomy combine with mandibular osteotomy. The implant group consisted of 10 patients with – 5.2 mm overbite and the surgery group consisted of 13 patients with – 5.1 mm overbite. They found that both methods were effective in treating anterior open bite with a 7mm increase in overbite on average (Kuroda et al., 2007a)..

Deguchi et al (2011) retrospectively analysed the outcomes of conventional edgewise and vertical elastics treatment and implant-anchored treatment to intrude molars in 30 patients with a more than 3 mm anterior open bite. They found that open bite correction with the conventional edgewise was achieved by extrusion of the maxillary and mandibular incisors. On the other hand, the correction of anterior open bite in the other group was achieved with molar intrusion. Despite the significant amount of molar intrusion in the implants group and of extrusion of incisors in the conventional edgewise group, most cephalometric values and PAR scores showed no significant differences two years after the treatment (Deguchi et al., 2011).

Although, mini-implants are reported to be an effective method to correct deepbite and anterior open bite malocclusion in many case reports and retrospective studies, their use is only supported by low quality evidence.

Correction of transverse discrepancy

Because of the advantage of stationary anchorage that miniscrews offer, correction of posterior cross bite or scissor bite is possible by using miniscrews. There are a few case reports that demonstrate different methods that can be used to correct the transverse discrepancy (Jeon et al., 2006; Tamamura et al., 2009; Ishihara et al., 2014). Unfortunately, there is lack of high standard studies examining the effectiveness of miniscrews in treating crossbite and scissors bite cases.

2.4 Methods of anchorage loss assessment

Quantifying treatment changes is crucial for orthodontists when treating a patient or investigating the effectiveness of different anchorage reinforcement methods. Traditionally, recording treatment changes is done by direct calculation on plaster dental casts or cephalometric radiographs. More recently, recording treatment changes can be achieved by superimposition of pretreatment and posttreatment digitised dental casts. Methods reported in the literature are shown in Table 2.

Cephalometric superimposition has been used widely as a method to evaluate treatment changes. It can be noted from Table 2 that the vast majority of studies evaluating anchorage loss have used cephalometric superimposition. It is interesting to note that different studies used different methods of superimposition. In most studies, superimposition of pretreatment and posttreatment cephalometric tracing was on a line connecting Sella and Nasion points (SN line), or the best fit to maxilla.

The most often used method of assessment of anchorage loss was by calculating the distance between the first molar and a fixed reference in the pretreatment then on the posttreatment cephalometric radiograph. Basha et al (2010) and Sharma et al (2012) used the pterygoid vertical plane as the reference plane on the cephalometric radiographs before and after the intervention and then calculated the difference in the horizontal movement of the first molar. Liu et al (2009) constructed the Frankfort plane as the x-axis and dropped a perpendicular plane through Sella as the y-axis. To determine changes in first molar, the acetate paper was overlaid on a grid with 1-mm scale. All of these three RCTs used the Cartesian coordinate system which identifies the location of one point by using two numerical coordinate (Niehrs, 2010).

Despite superimposition of serial lateral cephalometric radiographs being used widely to measure treatment outcomes such as tooth movement (Table 2), their use is accompanied with downsides such as the fact they represent 2-dimensional replicates for 3-dimensional objects, identification of landmark points is not always accurate and they are produced through radiation exposure (Deguchi et al., 2008; Ghafari et al., 1998a).

Gu and McNamara (2008) investigated the superimposition method on anatomical structures (routinely used method in orthodontics) with metallic implants (the gold standard that cannot be used at the present because of ethical issues). In this study, they used a sample of 10 subjects (age range 7.8 – 16.1 years) retrieved from a growth study conducted in the 1970s at University of California (Mathews and Ware, 1978; Gu and McNamara, 2008). In this study, cephalometric radiographs were taken in six stages of the cervical vertebral maturation (CV1-CV6). Gu and McNamara superimposed the six tracings on anatomical structures and then on the metallic implants and found major differences between the different methods of tracing. They found that the treatment outcomes greatly changed according to the used method of superimposition. Previous study by Isaacson et al (1976) reached a similar finding when they investigated treatment changes in four subjects of the Bjork growth study (1968).

To overcome the limitations of cephalometric radiographs for treatment outcome assessment, 3-deminsional measurement of dental casts was developed. Plaster dental casts have been used as the traditional tool for orthodontists to evaluate a patient's malocclusion in three-dimensions. They are appropriate for diagnosis, assessment of treatment progress, teaching and research purposes. However, their use is linked with problems such as breakage, loss, and the need for physical room for storage. In research interested in evaluating anchorage loss, the use of direct calculation on the plaster model is not popular (Table 2).

Table 2 Methods of anchorage loss assessment

Author	year	Study Type	Methods of anchorage loss assessment	Method of anchorage reinforcement	Methods of cephalometric superimposition	Comments
Lotzof et al.	1996	RCT	Acrylic guide made on initial models	Tip edge VS straight wire	Not mentioned	Split mouth technique
Wehbien et al.	1999	Cohort	Cephalometric superimposition + dental casts	TPA VS palatal implants	ANS/PNS	
Ashmore et al.	2002	Retrospective	3D study models superimposing	Headgear VS control	Not mentioned	
Xun et al.	2004	Case series	Cephalometric superimposition	Miniscrews	Published in Chinese	
Liou et al.	2004	Cohort	Cephalometric superimposition	Miniscrews	Best fit of maxilla / cranial base/ cranial vault	
Urias & Mustafa	2005	CCT	Cephalometric superimposition + dental casts	Bioprogressive VS standard edgewise	Maxillary regional superimposition	
Thiravenkatachri et al.	2006	Cohort	Cephalometric superimposition	Miniscrews	Palatal plane	
Heo et al.	2007	CCT	Cephalometric superimposition	2-step retraction VS en-mass retraction	Not mentioned	

Author	year	Study Type	Methods of anchorage loss assessment	Method of anchorage reinforcement	Methods of cephalometric superimposition	Comments
Hedayati et al.	2007	Cohort	Cephalometric superimposition	Miniscrews	Not mentioned	Cartesian coordinate system was used to assess molar movement
Wehbien & Gonller	2007	Cohort	Cephalometric superimposition	Palatal implants	ANS/PNS	
Qin & Mou	2008	CCT	Cephalometric superimposition	Miniscrews VS J-headgear	Published in Chinese	
Feldman & Bondemark	2008	RCT	Cephalometric superimposition	Headgear Vs. TPA VS onplant VS orthosystem implant	Pancherz sagittal-occlusion analysis	
Ma et al.	2008	RCT	Cephalometric superimposition	Miniscrews Vs. headgear	Not mentioned	Molar movement was not assessed
Shi et al.	2008	RCT	Cephalometric superimposition	Miniscrews Vs. headgear	Published in Chinese	
Upadhyay et al.	2008	Cohort	Cephalometric superimposition	Miniscrews VS headgear	Not mentioned	
Upadhyay et al.	2008	RCT	Cephalometric measurements	Miniscrews VS conventional anchorage reinforcement	Not mentioned	

Author	year	Study Type	Methods of anchorage loss assessment	Method of anchorage reinforcement	Methods of cephalometric superimposition	Comments
Lai et al.	2008	Retrospective	3D study models superimposing	Headgear VS miniscrews VS midpalatal implant	Not mentioned	
Wang et al.	2008	Retrospective	Cephalometric superimposition	Self-drilling miniscrews VS predrilled	Best fit of maxilla	
Zabalocki et al.	2008	Retrospective	Cephalometric superimposition	TPA	Palatal plane	
Zhou et al.	2008	Retrospective	Cephalometric superimposition	Miniscrews	Published in Chinese	
Chen et al.	2008	Retrospective	Cephalometric superimposition	Miniscrews	SN line	
Yuo et al.	2008	Retrospective	Cephalometric superimposition	Miniscrews VS headgear	SN line	
Kim et al.	2008	Retrospective	Cephalometric superimposition	Miniscrews	Not mentioned	
You et al.	2008	Retrospective	Cephalometric superimposition	TPA VS headgear VS miniscrews	SN line	
Kuroda et al.	2009	CCT	Cephalometric superimposition	Miniscrews VS headgear	Not mentioned	

Author	year	Study Type	Methods of anchorage loss assessment	Method of anchorage reinforcement	Methods of cephalometric superimposition	Comments
Liu et al.	2009	RCT	Calculation on cephalometric	TPA VS miniscrews	Not mentioned	Cartesian coordinate system was used to assess molar movement by using Frankfort horizontal plane as x axis
Stivaros et al.	2010	RCT	3D study models superimposing	TPA VS Nance	Not mentioned	
Basha et al.	2010	RCT	Calculation on cephalometric	miniscrews VS control	Not mentioned	Pterygoid vertical plane used as a reference for molar mesial movement
Xu et al.	2010	RCT	Cephalometric superimposition	2-step retraction VS en-mass retraction	palatal plane and ANS	
Mezomo et al.	2011	RCT	Acrylic guide made on initial models	self-ligations brackets VS conventional brackets	Not mentioned	
Borsos et al.	2011	RCT	Cephalometric superimposition	TPA VS palatal implants	Not mentioned	
Koyama et al.	2011	Retrospective	Cephalometric superimposition	Miniscrews VS headgear and intermaxillary elastics	Zygomatic process / palatal curvature	

Author	year	Study Type	Methods of anchorage loss assessment	Method of anchorage reinforcement	Methods of cephalometric superimposition	Comments
Park et al.	2012	CCT	3D study models superimposing	Miniscrews VS TPA and/or headgear	Not mentioned	
De Lima Araujo et al.	2012	Cohort	Cephalometric superimposition	Miniscrews	Palatal plane and ANS	
Sharma et al.	2012	RCT	Calculation on cephalometric	TPA VS miniscrews	Not mentioned	Pterygoid vertical plane used as a reference for molar mesial movement
Gokce et al.	2012	RCT	Cephalometric superimposition	Miniscrews VS including second molar	Published in Turkish	
Machibya et al.	2013	Retrospective	Cephalometric superimposition	Self-ligations brackets VS conventional brackets	Pancherz sagittal-occlusion analysis	
Lee et al.	2013	Retrospective	Cephalometric superimposition	Headgear VS Miniscrews	Anterior cranial base (SN)	
Sandler et al.	2014	RCT	3D study models superimposing	Nance VS headgear VS miniscrews	Not mentioned	
Al Sibaie et al.	2014	RCT	Cephalometric superimposition	TPA VS miniscrews	Anterior cranial base (SN)	
Monga et al.	2016	Retrospective	Cephalometric superimposition	Indirect loading of miniscrews	Anterior cranial base (SN)	

Author	year	Study Type	Methods of anchorage loss assessment	Method of anchorage reinforcement	Methods of cephalometric superimposition	Comments
Juneja et al.	2014	Retrospective	Cephalometric superimposition	Self-ligations brackets VS conventional brackets	SN line	
Benson et al.	2007	RCT	Cephalometric superimposition	Mid palatal vs. headgear	SN line	
Borsos et al.	2012	RCT	Cephalometric superimposition	Mid palatal vs. TPA	Not mentioned	
Davody et al.	2013	Cohort	Cephalometric superimposition	Miniscrews VS mushroom loops for space closure	Anterior cranial base (SN)	

Lotzof, Fine and Cisneros (1996) compared anchorage loss between the Tip-Edge appliance and "A-company" straight wire appliance in a randomised clinical trial (Lotzof et al., 1996). Anchorage loss was the amount of movement of molars in millimetres determined by direct measurement on dental casts. To measure molar movement, they fabricated an acrylic palatal plug for each initial maxillary cast and then fitted it on final maxillary models. This plug had reference wires embedded in acrylic and extended to canine cusps and central fossa of first molars. The same technique was used by Mezomo et al. in a RCT who assessed anchorage loss in self-ligating and conventional brackets (Mezomo et al., 2011). Figure 7 shows an illustration of the acrylic palatal plug used for measurements.

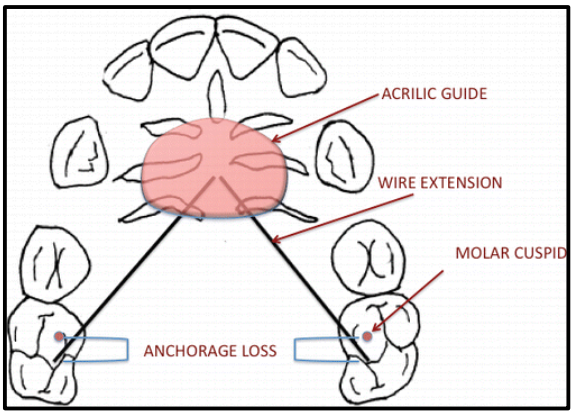


Figure 7 The acrylic guide constructed in the initial study model (T0), with two wires extending to mesiopalatal cusp of the first molars. Adaptation of the final study model (T3) allowed the measurement of anchorage loss. (Mezomo et al., 2011)

Advances in technology enabled orthodontists to create digital models that have a promising future to overcome the limitations of cephalometric superimposition and stone dental casts. Digitised dental models offer the advantage of immediate access to patients' records, performance of electronic setups and patient's records can be transferred instantly for consultation (De Luca Canto et al., 2015).

2.4.1 Stability of palatal rugae

Three dimensional measurements of dental casts requires a stable region to be employed as a reference point. Lebret et al (1962) suggested that the palatal rugae are stable, in particular the ones near the midline (Lebret, 1962). Peavry and Kendrick (1967) studied treatment changes in 15 patients treated with premolar extraction. They concluded that the ends of the lateral palatal rugae were affected

by the movement of canines and premolars. Unfortunately they did not study the ends of the median palatal rugae (Peavy Jr and Kendrick, 1967). However, Van der Linden (1978) studied 65 cases for 10 years and found that lateral palatal rugae were stable especially the end points of third lateral rugae. Similarly to Peavry and Kendrick, Van der Linden did not study median palatal rugae extensively.

Almeida et al (1995) studied the effect of headgear, functional appliance and growth alone (control group) on the stability of median palatal rugae. They evaluated initial and final casts of 94 patients who enrolled in a RCT investigating headgear treatment for class II. They concluded that the median ends of palatal rugae could be used as stable reference points in the three groups. On the other hand, they found that the lateral ends of the palatal rugae had changed during the period of investigation not only in the treatment group, but in the control group as well.

Elbaily et al (1996) studied the effect of orthodontic treatment with and without extraction on 57 adult patients using the Almeida et al (1995) method. Interestingly, he found the third lateral and median ends of palatal rugae were stable while Almeida et al found the first one was more stable (Bailey et al., 1996).

In a more recent publication, Jang et al (2009) used three metallic miniscrews placed in the palate and ligated to transpalatal arch (Figure 8) for anchorage reinforcement in 10 patients who needed extraction as a part of their orthodontic treatment. Beside anchorage reinforcement, the miniscrews were used as stationary landmarks for superimposing the digital dental cast of the patients before and after treatment to validate the stability of palatal rugae. They concluded that the median point of the third palatal rugae were stable and reliable point for the casts superimposition.

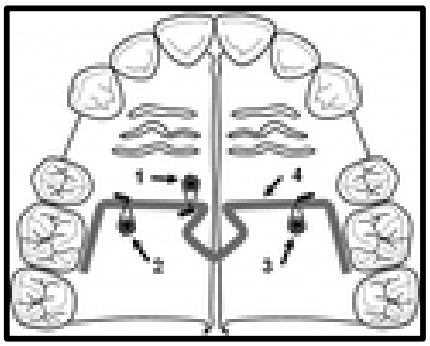


Figure 8 Miniscrews were placed in the palate and ligated to transpalatal arch with ligature wires (Jang et al., 2009)

It appears from previous investigations (Lebret, 1962; Almeida et al., 1995; Bailey et al., 1996; Jang et al., 2009) that palatal rugae, especially the median ends, can adequately be used as an anatomical reference point to evaluate treatment changes even in cases when headgear is used or premolar extraction is performed.

2.4.2 Tooth movement measurements on digital study models.

In 2002, Ashmore et al. suggested a method to record movement of the first molar from headgear use. In this study, they obtained records of 36 patients with class II malocclusion and randomised to headgear treatment as a part of randomised clinical trial conducted in Pennsylvania University (Ghafari et al., 1998b). In the Pennsylvania study, the authors compared a headgear to Fränkel function regulator. Ashmore and her colleagues obtained records for 38 patients allocated to no treatment group from a randomised clinical trial conducted in Florida (Keeling et al., 1998). In the Florida trial, the no treatment group was compared to a Bionator or headgear/bite plane. It is interesting that Ashmore et al. did not obtain both samples from the Florida study. This could be explained by the fact that the headgear was accompanied by bite plane. The measurements in Ashmore et al. study were done by recording the dental casts using 3D digitizer (Microscribe 3DX, Immersion Corporation, San Jose, Calif) and then using LabVIEW software program (National Instruments, Austin, Tex). The authors derived the spatial data of each model then used the best fit of the palatal rugae areas. After before and after models were oriented on the same coordinate system, then molar movement was calculated.

It is interesting in this study to find that the reliability of this technique was poor for computing the rotation for the molar when the measurements were repeated for the second time. However, the authors did not mention how much washout period was used between the two occasions of measurements. Although, Ashmore et al. study is retrospective, the sample was obtained from different randomised clinical trials and they did not compare the validity of their method against other methods, their study provided an alternative method to measure tooth movement.

In 2003, Keilig et al suggested superimposition of digitised casts before and after treatment as a method of determining tooth movement (Keilig et al., 2003). They digitized before and after treatment dental casts of 20 patients treated either with

positioner or fixed appliances. Using surface-surface matching algorithms on the palate of before and after treatment dental casts, they determined the amount of tooth movement. The authors concluded that this method measured tooth movement with accuracy of 0.2 mm in translation and 1 degree in rotation. As with the Ashmore et al study, Keilig et al study was retrospective, and they did not compare their method against other methods to investigate the validity of their method.

Cha et al. (2007) performed an interesting study to investigate the accuracy of measurements on digital dental casts when compared to the measurements on cephalometric superimposition. They obtained the records of 30 patients who went through orthodontic treatment involving extraction. After digitizing the dental models with INUS dental scanning solution®, which consists of a 3D scanner (topometric and photometric 3D scanner, Breuckmann Inc., Germany, resolution 8 μ m, reliability ±15 μ m), they superimposed before and after treatment models. The superimposition was performed on the best fit method on the palatal region using Rapidform 2002 software (Rapidform 2002®, INUS Technology Inc., Seoul, South Korea). In comparison to tooth movements that were measured using cephalometric superimposition of before and after treatment radiographs, no statistical difference was found between the two methods. They concluded that the three dimensional measurement is as accurate as the cephalometric superimposition method. Although this was a retrospective study, it provided a comparison of the accuracy of three dimensional superimposition against cephalometric superimposition method.

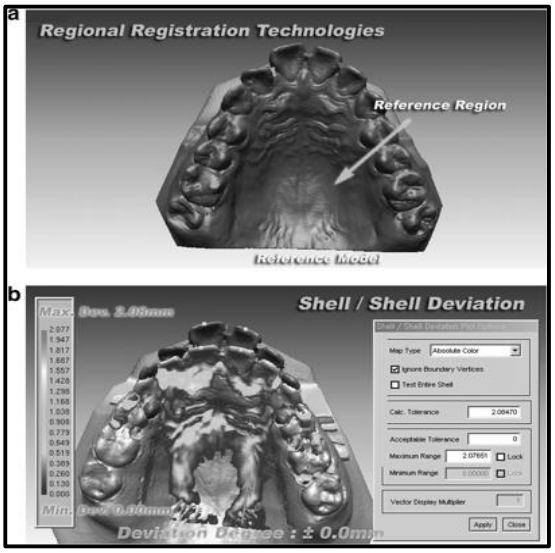


Figure 9 Reference region used for superimposition (a) The superimposed models (b) (Cha et al., 2007)

An interesting study performed in Manchester by Thiruvenkatachari et al investigated the accuracy of measurements on digital dental casts (Thiruvenkatachari et al., 2009). In this study, they scanned the models using a laser scanner (VIVID 910i, Konica Minolta Sensing, Tokyo, Japan) and then they used Rapidform 2006 software (INUS Technology and Rapidform Inc, Seoul, Korea) to manipulate the scans.

After scanning the models, the before and after treatment models were superimposed using the palatal region by marking lateral and medial end points of the palatal rugae then by marking a mushroom-like area on the region (Figure 10,11). They first validated the scanner and software by two methods. In the first method, they scanned 50 models and then measured the intermolar width using the software and then they repeated the measurements on the plaster models using digital calliper. They found the difference between the measurements to be 0.06mm which was statistically insignificant.

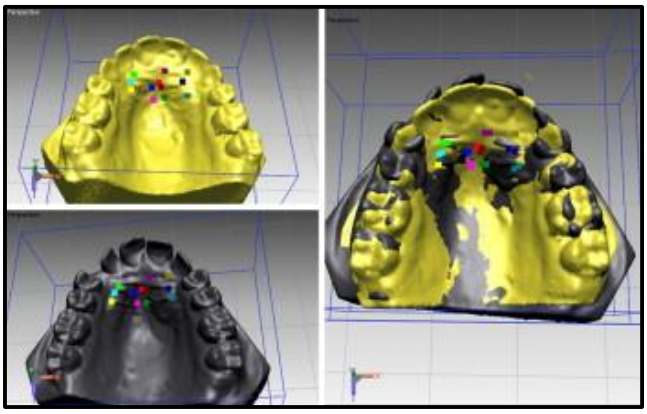


Figure 10 . Initial registration by identifying stable points on the palate (Thiruvenkatachari et al, 2009)

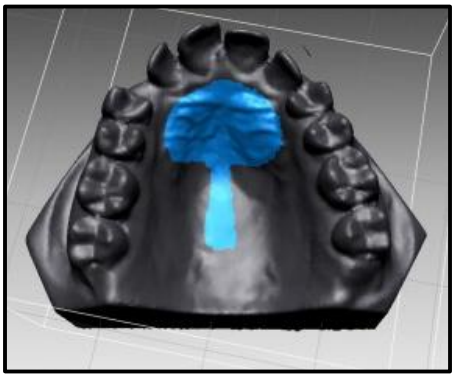


Figure 11 Regional registration by drawing a mushroom-shaped area on the palate (Thiruvenkatachari et al, 2009)

In the second method of validation, they prepared an experimental model attached to a metal plate and they suspended a molar with a jig fixed to the molar plate (Figure 12).

This model design allowed for the molar movement to be accurately measured with digital callipers. The molar was moved by 0.5 mm buccolingually and anteroposteriorly. The molar movement was analysed by three dimensional measurement method using Rapidform software as well as by the digital calliper. The difference between the two methods was 0.023 mm for anteroposterior movements and 0.007 mm for buccopalatal movements. This difference was statistically insignificant.

Figure 12 an experimental model: a maxillary study cast is fixed to a metal plate (Thiruvenkatachari et al, 2009)

The final stage of this study was to compare measurements from cephalometric methods of molar movement with measurements made with the laser scanner. They obtained the records of 22 patients who had participated in a randomised clinical trial by Benson et al (2007) that investigated anchorage effectiveness of headgear in comparison to midpalatal osseointegrated implants. The casts were scanned and then the amount of molar movement measured. They compared the measurements obtained from three dimensional superimposition to the measurements obtained from the cephalometric radiograph superimposition. The difference between the two methods was statistically insignificant.

Thiruvenkatachari and his colleagues concluded that measurements on 3D models are accurate and reliable and could be used as an alternative to cephalometric radiographs superimposition. The disadvantage of this method was the cost (£ 40,000 for the scanner and the software) and the time required to undertake the scanning and the analysis (30 minutes per cast).

In summary, different methods such as direct calculation on dental casts, measurements on superimposed cephalometric tracings and measurements on superimposed digital models have been suggested for assessing anchorage loss and tooth movement. Measurements of cephalometric tracings were used more than any

other methods in studies despite its limitations (Table 2). Measurements on superimposed digital models can be alternative to measurements of superimposed cephalometric tracings. The medial ends of the palatal rugae and the third rugae in particular are stable and can be used for the superimposition of digital models.

Chapter 3. Miniscrews Failure and its Factors: Systematic Review and Meta-Analysis.

3.1 Introduction

Miniscrews should remain stationary when orthodontic force is applied to effectively support anchorage. Failure of miniscrews could be a result of many factors. These factors are design, material, patient, or clinician related.

Miniscrew failure is a problem that the orthodontist faces when he/she uses them. It is important for the orthodontist to understand the factors that make miniscrews fail. In previous published studies and conference lectures, several orthodontists have made suggestions about making miniscrews more stable and facilitating their use. These suggestions were based on studies that investigated the reasons for miniscrews failure.
Approaching the literature systematically and selecting study designs that carefully tackle the problem is important. For this reason, a systematic review and meta-analysis based on the aggregated failure rate of miniscrews has been undertaken, including a subgroup analysis of the factors that might contribute to miniscrew failure.

A systematic review follows a sequence that is largely similar to the evidence-based practice definition (Rosenberg and Donald, 1995). The sequence of performing systematic review as suggested in the literature (Cook et al., 1997; Lau et al., 1997) is the following:

1. specify a research question
2. decide the type of studies expected to answer the research question
3. search the literature
4. decide on the inclusion and exclusion criteria
5. perform a critical appraisal of each included study
6. perform a meta-analysis
7. publish the results of the systematic review

A meta-analysis works in conjunction with a systematic review as an additional step to the review. It statistically combines all of the results from similar quantitative studies. Normally, meta-analysis tries to measure the average estimation of an effect size across several studies on the same topic. The effect size is used as an estimate of

the treatment effect or the correlation between two variables. The effect size can be computed in different forms, such as odds ratio, mean difference, correlation coefficient or risk ratio. Usually, meta-analysis follows a sequence in which the effect size of each study is determined, followed by a calculation of the summary effect of all of the included studies (Egger et al., 1997).

Papageorgiou, Zocakis and Papadopoulos (2012) carried out a meta-analysis investigating miniscrews failure rate. They included randomised clinical trials and prospective cohort studies only. They found out that that the failure rate was 13.5%. The aim of this meta-analysis was to give an update to Papageorgiou, Zocakis and Papadopoulos (2012) meta-analysis and to reassess their included studies.

3.2 Methods and materials

3.2.1 Included studies

The included studies in this systematic review were human clinical trials and prospective cohort studies that investigated the use of orthodontic miniscrews and were published in English. The search strategy can be found in Appendix 2 (page 222). Articles on miniscrews with a diameter greater than 2 mm, in vitro studies, animal studies, case reports and case series and review articles from the original meta-analysis (2012) and updated research results were excluded. In cases of unclear study design, the author was contacted for further information. Relevant articles were identified first after reading their titles and abstracts.

The full text of the potential articles was assessed for eligibility by two reviewers (Fahad Alharbi & David Bearn). One reviewer (FA) independently extracted data using a customized data extraction form developed by Papageorgiou et al. (2012). The following information was included for each study: year of publication, setting, study design, number of miniscrews and their characteristics, success criteria, failure rate and the handling of failure.

3.2.2 Type of participants.

Patients of any age treated with fixed appliances and miniscrews (diameter ≤ 2mm).

3.2.3 Type of interventions.

Miniscrews (diameter ≤ 2mm) used at any stage of the treatment and for any purpose, adjunctive to fixed appliance therapy.

3.2.4 Type of outcomes.

The primary outcome of this review was the failure rate of miniscrews. The secondary outcomes were factors associated with mini-screw failure.

3.2.5 Identification of studies.

To identify appropriate studies for this systematic review, an update to a systematic review carried out by Papageorgiou, Zocakis and Papadopoulos (2012) (Papageorgiou et al., 2012) was performed using their search strategies (Appendix 2).The following databases were searched: MEDLINE via PubMed (February 2011-September 2015); Cochrane Database of Systematic Reviews (February 2011-September 2015); Scopus (2011- 2015) and Ovid (2011-2015).

3.2.6 Assessment of risk of bias in the included studies.

Clinical trials were assessed for risk of bias using the Cochrane collaboration's tools (Higgins et al., 2011). Prospective cohort studies were assessed for risk of bias using the Newcastle-Ottawa Scale (Wells et al., 2000). Each cohort study was assigned a score ranged between zero (lowest quality) and nine (highest quality). In case of disagreement between the two reviewers, a mutual decision through discussion was made.

3.2.7 Data synthesis and meta-analysis.

The statistical methods that are usually used in meta-analyses were employed using either fixed or random model methods. The fixed effect model depends on the premise that the treatment effect of the included studies is the same. That implies that the effect size, considering the role of chance, was the same in all studies.

On the other hand, the random effect model is another method that accepts that the genuine treatment effect in the individual studies may not be identical across all studies. In medical studies, the random effect model is used more often as it takes the level of heterogeneity into account. Medical studies differ from each other due to the different study design, sample size and characteristics, different statistical tests and ways of performing the measurements (Borenstein et al., 2009).
For this meta-analysis, analyses were performed using the statistical software Comprehensive Meta-Analysis (Biostat Inc., Englewood, NJ, USA), with the random-effect model. Pooled estimates with 95% Confidence Intervals (CI) of the incidence of miniscrews failure were computed.

3.2.7.1 Heterogeneity.

Heterogeneity is the extent to which the effect sizes contrast from each other. In meta-analysis, it is important to utilize measurable tests to investigate whether the differences between the effect sizes in different studies are greater than what they would normally be, by chance. Assuming that this is the case, then the observed effects are said to be heterogeneous. On the other hand, homogeneity is the situation where the variability observed between effects sizes is expected to be explained by chance or sampling error. Heterogeneity in this meta-analysis was assessed by calculating the Q statistics and corresponding P value and by calculating the I^2. (Higgins and Thompson, 2002).

The Q test is a common test to assess whether true between-study heterogeneity exists within a meta-analysis. A significant Q test would indicate that this is the case. However, if the number of included studies in a meta-analysis is low, the Q test has low power to detect the between-study heterogeneity. Conversely, if the number of included studies is large, then the Q test has much more power (Higgins et al., 2003).

I^2 is the statistical measurement of heterogeneity. It evaluates the degree of heterogeneity between the included studies in the meta-analysis. Higgins and Thompson (2002) pointed out that I^2 represents the variability of the effect size across the studies that is explained by the heterogeneity between the studies. For example, an I^2 equal to 25% means that a quarter of the aggregate variability among

the effect sizes is explained by study heterogeneity. They suggested a rule for interpreting the extent as 25% means low heterogeneity, 50% means medium heterogeneity, and 75% means high heterogeneity.

3.2.7.2 Publication Bias.

Publication bias is considered as one of the most concerning issues in meta-analyses. It happens in cases when studies that do not yield statistical or clinical significant results are not published. Besides, there are other forms of bias, like language bias, where studies only written in English are included in the meta-analysis (as is the case with this current study) or non-English studies are only written in English if they have significant findings.

Researchers who perform a meta-analysis refer to publication bias, but this is not the only possible bias in meta-analysis included in the broader expression "dissemination bias". As a rule, when the investigation is impacted by the accessibility of the research findings, we ought to talk about dissemination bias. This depends on whether a study is distributed as well as when, where and in which format this happens. For instance, language bias is connected to the way in which studies without significant results are often only published in languages other than English. This means that it will be difficult to find such studies with negative results. Researchers attempt to publish their positive findings in English language journals while negative findings are more likely to be published in local journals. As a result, bias may be present in a meta-analysis due to the inclusion of studies that have been published in English only. Although there are several European journals published in languages other than English and still indexed in the large database including Scopus, Medline and Embase, this is not the same case for journals published in developing countries. Clearly, it will not be easy to find research report that are not published in a journal indexed in a major database (Mueller et al., 2006).

I evaluated the publication bias in this meta-analysis by inspecting the funnel plot asymmetry. Funnel plot is a graphical method for identifying publication bias. It arises from plotting the effect size on the X-axis against the sample size or other indicator of the precision of the effect size on the Y-axis. The effect size of small studies will be distributed at the bottom of the funnel, while the large studies will

appear at the top of the funnel. In the absence of bias, the studies will be distributed in the form of a funnel shape (Sterne et al., 2011).

Moreover, I used two statistical methods to produce significance tests in order to recognize publication bias: Begg and Mazumdar's method (Begg and Mazumdar, 1994) and Egger's method (Egger et al., 1997). Begg's method is considered one of the first rank correlation tests for assessing publication bias. They proposed testing the study variance independence and effect size utilizing the non-parametric Kendall's method. Begg's approach became popular due to its simplicity, and was thought to be a significant powerful test where the meta-analysis includes many studies. On the other hand, the test has low power if the meta-analysis has a low number of studies (Sterne et al., 2000).

Like Begg's approach, Egger's test is used to quantify the captured bias in a funnel plot. Unlike Begg's approach, Egger's is carried out using the linear regression method rather than a correlation rank method. If the P value is above 0.05, this means that there are no grounds for dismissing the null hypothesis that symmetry exists in the funnel plot. Therefore, no evidence that dissemination bias exists in the studies included in the meta-meta-analysis.

3.2.7.3 Subgroup analysis.

The rationale behind dividing the main sample size in to subgroups is to make comparisons between them. Dividing the participants into subgroups is performed based on factors that may have an impact on the outcome, known as effect modifiers, explanatory variables or covariates. Additionally to investigating the heterogeneity, subgroup analyses can answer specific questions concerning particular groups of participants, types of interventions or type of studies. In this meta-analysis, the subgroup analyses were pre-planned and pre-specified (a priori). The selected factors were:

1. Diameter of TAD ((small (≤ 1.4mm), medium (1.5-1.7mm), large (>1.7mm))
2. Length of TAD ((≤8mm), (>8mm))
3. Jaw (maxilla or mandible)
4. Age (≤18 years, >18 years)
5. Loading (immediate, delayed)
6. Design (self-drilling, non-self-drilling)

7. Smoking habit
8. Type of mucosa (keratinized tissue or not)

3.2.7.4 Sensitivity analysis.

Sensitivity analysis is performed to determine how the findings of a systematic review/meta-analysis may change after modifying the data, for example, in changing the inclusion criteria which had been used. Thus, after the analysis, if changing makes little or no difference to the overall results, it means that the findings of the meta-analysis are robust. If the key findings change considerably, then they must be interpreted with caution (Higgins and Green, 2008).

Further meta-analyses were conducted to explore the effect of factors such as the study design (RCT or cohort) and sample size (100 Miniscrews and more) on the effect size.

3.3 Main results.

3.3.1 Study characteristics.

Out of 8110 studies, 7915 studies did not qualify for the systematic review and meta-analysis on the basis of title and abstract. 152 of the disqualifying studies were excluded after their full texts were retrieved. They were laboratory studies, retrospective studies, systematic reviews or not relevant. The final sample was 43 studies that met the primary inclusion criteria. The included studies were 16 randomised clinical trials and 27 prospective cohort studies. Five studies (Upadhyay et al., 2012; Ma et al., 2008; Sar et al., 2013, Khanna et al., 2014; Falkensammer et al., 2014) were not included in the meta-analysis due to a lack of the statistical information needed to compute the effect sizes. However, they were included in the quality assessment of the studies. The authors were contacted when necessary to obtain more information and, if no reply was received, the study was excluded.

The main characteristics of the 43 included studies which collectively included 3130 miniscrews are detailed in Table 3. Table 3 shows that 33 (77%) of the studies were based in university settings, while the other 10 studies took place in either private, hospital or unknown settings. There was considerable variation between the brand

names of the miniscrews used in the included studies and in the dimensions of the inserted miniscrews. Table 3 shows that the recorded failure rate of miniscrews in the included studies also ranged from zero to 40.8%.

3.3.2 Characteristics of the participants.

1605 patients were included in the analysis. Most studies included both males and females. Females only were recruited in 4 studies (Basha 2010, Upadhyay 2008a, Upadhyay 2009; Upadhyay 2012). Two studies did not report on the gender of the patients (El-Beialy et al., 2009; Hedayati et al., 2007).

3.3.3 Characteristics of the intervention.

There was considerable variation between the brand names of the miniscrews used in the included studies. The diameter of the inserted miniscrews ranged from 1.2 mm to 2 mm and the length from 5 mm to 15 mm (Table 3). Uses of miniscrews also varied between the studies. The vast majority of miniscrews were used to reinforce orthodontic anchorage for retraction of anterior teeth. However, other uses of miniscrews were reported, such as incisor or molar intrusion, molar protraction and molar uprighting.

3.3.4 Risk of bias of included studies.

3.3.4.1 Clinical trials

The random sequence generation domain was assessed to be adequate in 9 trials as shown in Table 5 (Sharma et al., 2012; Aboul Ela et al., 2011; Liu et al., 2009; Sandler et al., 2014; Upadhyay et al., 2008a; Falkensammer et al., 2014; Ma et al., 2008; Bechtold et al., 2013).The remaining trials were assessed as having high risk of bias (Upadhyay et al.,2008b; Basha et al., 2010; Chaddad et al., 2008) or unclear risk (Garfinkle et al.,2008; Lehnen et al., 2009; Turkoz et al., 2010; Wiechmann et al., 2007). Allocation concealment domain was graded as having low risk of bias in five trials only (Sharma et al., 2012; Sandler et al., 2014; Upadhyay et al., 2008; Alsibaie & Hajeer et al.,2014; Falkemsammer et al., 2014). The rest of the studies were assessed as having unclear risk of bias or high risk of bias.

The blinding of participants and personnel was not possible in the included trials due to the nature of orthodontic treatment. However, blinding of assessors was possible and was carried out in 6 trials (Sharma et al., 2012; Lehnen et al., 2011; Sandler et al., 2014; Alsibaie &Hajeer, 2014; Falkensammer et al.,2014; Maet al., 2008), the remaining ten studies either blinding was not performed or the reporting was not adequate.

There were no dropouts in the included trials or the dropouts were reported on. Therefore, all included trials were assessed as having low risk of bias regarding reporting the outcomes. Selective bias domain was judged to have a low risk of bias only in three trials (Sharma et al., 2012; Sandler et al., 2014; Alsibaie & Hajeer et al., 2014). The remaining studies were judged to have unclear risk of bias because no information was reported to permit judgment.

The summary judgment of risk of bias were assessed to be low in four trials only (Sharma et al., 2012; Sandler et al., 2014; Alsibaie & Hajeer., 2014; Falkensammer et l., 2014). The remaining trials were judged to have overall high risk of bias after assessment all six domains was performed.

3.3.4.2 Prospective Cohort studies.

Quality assessment of prospective cohort studies was based on three domains: participant selection, comparability of the groups and finally, the outcome assessment. The vast majority of the prospective cohort studies had medium quality according to Newcastle-Ottawa Scale as shown in Table 6. Two studies were judged to have high quality (Upadhyay et al., 2009; Davoody et al., 2012) and one study was judged to have low quality (Palot-Ozsoky et al., 2009).

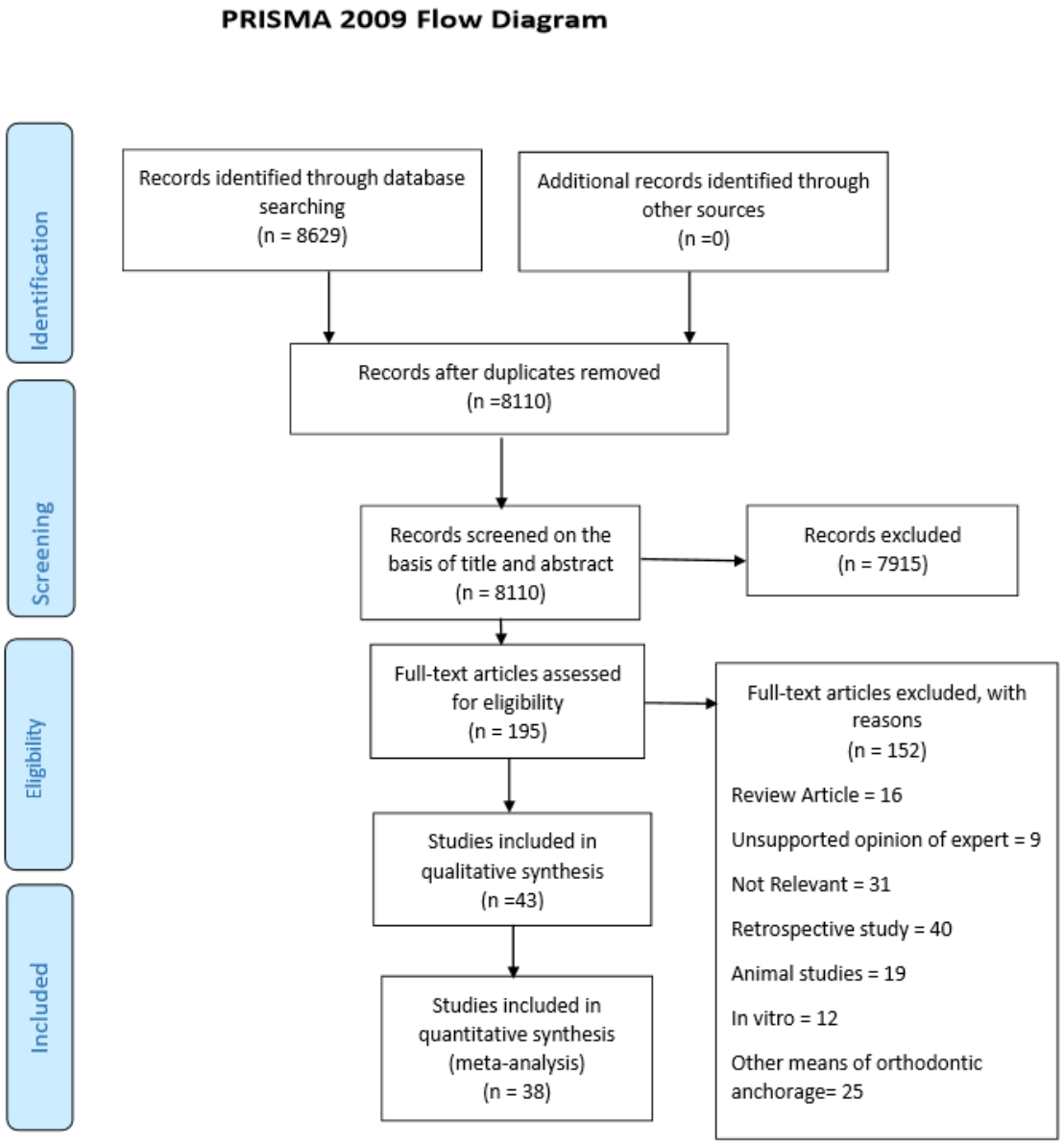


Figure 13 Flow chart of the selection of studies

Table 3 Characterstics of included studies

Author	Design	Setting	Number of patients	Number of miniscrews		Type of miniscrews	Dimensions		Success criteria	Failure rate (%)	Handling of failure
				Total	**Per patient (per Jaw)**		**Diameter (mm)**	**Length (mm)**			
(Aboul-Ela et al., 2011)	RCT	University	13	26	2 (2)	AbsoAnchor (Dentos,Daegu,Korea)	1.3	8	Stability	7.7	Repositioned
(Alves et al., 2011)	CCT	University	15	41	2/3 (2/3)	(INP,São Paulo,Brazil)	1.4/2	6/8	Not recorded	14.6	Replaced
(Apel et al., 2009)	PCS	University	25	76	2/4 (2)	Tomas-pin (Dentaurum,Ispringen,Germany)	1.6	8	Stability/ Infection	10.5	Excluded
(Basha et al., 2010)	RCT	University	14	14	2 (2)	Stainless steel	1.3	8	Stability	28.6	Replaced
(Bayat and Bauss, 2010)	PCS	Private	88	110	1-4 (1/2)	LOMAS (Mondeal Medical Systems,Tuttlingen,Germany)	2	7/9/11	Stability/ Infection	18.2	Not recorded
(Berens et al., 2006)	PCS	Private	85	239	1-3 (1/2)	AbsoAnchor (Dentos,Daegu,Korea)/Dual-Top (Jeil Medical,Seoul,Korea)	1.4/1.8/2	Not recorded	Stability	15.1	Rescrewed/ excluded

Author	Design	Setting	Number of patients	Number of miniscrews		Type of miniscrews	Dimensions		Success criteria	Failure rate (%)	Handling of failure
				Total	Per patient (per Jaw)		Diameter (mm)	Length (mm)			
(Blaya et al., 2010)	PCS	University/ private	30	30	1 (1)	Sin Implant System (São Paulo,Brazil)	1.2	10	Stability	0	Not recorded
(Chaddad et al., 2008)	RCT	Not recorded	10	32	2/4 (2)	C-Implant (Implantium,Seoul ,Korea)/Dual-Top (Jeil Medical,Seoul,Kor ea)	1.4-2	6-10	Stability/ Infection/ Treatment completion	12.5	Not recorded
(Cheng et al., 2004)	PCS	University	44	92	Not recorded	Leibinger (Freiburg,German y)/Mondeal (Tuttlingen,Germa ny)	2	5-15	Stability/ Infection/ Treatment completion	8.7	Not recorded
(El-Beialy et al., 2009)	PCS	University	12	40	Not recorded	AbsoAnchor (Dentos,Daegu,Ko rea)	1.2	8	Stability	17.5	Excluded
(Garfinkle et al., 2008)	CCT	University/ private	13	82	4/8 (4)	Osteomed (Addison,Tex)	1.6	6	Stability/ Treatment completion	19.5	Not recorded

Author	Design	Setting	Number of patients	Number of miniscrews		Type of miniscrews	Dimensions		Success criteria	Failure rate (%)	Handling of failure
				Total	Per patient (per Jaw)		Diameter (mm)	Length (mm)			
(Gelgör et al., 2004)	PCS	University	25	25	1 (1)	IMF Stryker (Leibinger,Germany)	1.8	14	Stability	0	Not recorded
(Hedayati et al., 2007)	PCS	University	10	27	3 (1/2)	Orthognathic screws	2	9/11	Stability	18.5	Repositioned
(Herman et al., 2006)	PCS	Not recorded	16	49	1/2 (1/2)	Ortho Implant (IMTEC,Ardmore, Okla),Sendax MDI	1.8	6/8/10	Stability	40.8	New/Excluded
(Kim et al., 2010a)	PCS	University	25	50	2 (2)	C-Implant (Implantium,Seoul ,Korea)	1.8	8.5	Stability	4	Replaced
(Lehnen et al., 2011)	RCT	Not recorded	25	60	2 (2)	Tomas-pin (Dentaurum,Ispringen,Germany)	1.6	8	Not recorded	11.7	Excluded
(Liu et al., 2009)	RCT	Not recorded	34	68	2 (2)	(Cibei,Ningbo,China)	1.2	8	Stability	11.8	Replaced
(Luzi et al., 2007)	PCS	University	98	140	Not recorded	Aarhus Mini-Implants (Medicon,Germany)	1.5/2	9.6/11.6	Stability/ Treatment completion	15.7	Excluded

Author	Design	Setting	Number of patients	Number of miniscrews		Type of miniscrews	Dimensions		Success criteria	Failure rate (%)	Handling of failure
				Total	Per patient (per Jaw)		Diameter (mm)	Length (mm)			
(Miyazawa et al., 2010)	PCS	University	18	44	Not recorded	(Jeil Medical,Seoul,Korea)	1.6	8	Treatment completion	9.1	Not recorded
(Motoyoshi et al., 2006)	PCS	University	41	124	1-4 (1/2)	ISA orthodontic implants (BIODENT,Tokyo ,Japan)	1.6	8	Stability	14.5	Not recorded
(Motoyoshi et al., 2007a)	PCS	University	57	169	1-4 (1/2)	(BIODENT,Tokyo ,Japan)	1.6	8	Stability/ Treatment completion	14.8	Not recorded
(Motoyoshi et al., 2007b)	PCS	University	32	87	Not recorded	ISA orthodontic implants (BIODENT,Tokyo ,Japan)	1.6	8	Stability/ Treatment completion	12.6	Not recorded
(Motoyoshi et al., 2010)	PCS	University	65	209	1-4 (1/2)	ISA orthodontic implants (BIODENT,Tokyo ,Japan)	1.6	8	Stability/ Treatment completion	11.5	Not recorded
(Motoyoshi et al., 2009)	PCS	University	52	148	Not recorded	ISA orthodontic implants (BIODENT,Tokyo ,Japan)	1.6	8	Stability	9.5	Excluded

Author	Design	Setting	Number of patients	Number of miniscrews		Type of miniscrews	Dimensions		Success criteria	Failure rate (%)	Handling of failure
				Total	Per patient (per Jaw)		Diameter (mm)	Length (mm)			
(Polat-Ozsoy et al., 2009)	PCS	University	11	22	2 (2)	AbsoAnchor (Dentos,Daegu,Korea)	1.2	6	Stability/ Infection	13.6	Replaced
(Thiruvenkatachari et al., 2006)	PCS	University	10	18	1/2 (1)	Titanium microimplant	1.3	8	Stability	0	Not recorded
(Türköz et al., 2011)	RCT	University	62	112	1/2 (1/2)	AbsoAnchor (Dentos,Daegu,Korea)	1.4	7	Stability	22.3	Not recorded
(Upadhyay et al., 2008a)	RCT	University	33	72	4 (2)	Modified Ti fixation screws	1.3	8	Stability	6.9	Replaced
(Upadhyay et al., 2008b)	CCT	University	30	30	2 (2)	Modified Ti fixation screws	1.3	8	Stability	10	Replaced
(Upadhyay et al., 2009)	PCS	University	40	46	2 (2)	Ti mini-implants	1.3	8	Not recorded	4.3	Replaced
(Wiechmann et al., 2007)	RCT	Not recorded	49	133		AbsoAnchor (Dentos,Daegu,Korea)/Dual-Top (Jeil Medical,Seoul,Korea)	1.2/1.6	5-10	Stability/ Treatment completion/ infection	23.3	Not recorded

Author	Design	Setting	Number of patients	Number of miniscrews		Type of miniscrews	Dimensions		Success criteria	Failure rate (%)	Handling of failure
				Total	Per patient (per Jaw)		Diameter (mm)	Length (mm)			
(Upadhyay et al., 2012)	PCS	University	34	28	2 (2)	Ti mini-implants	1.3	8	Not recorded	Not recorded	Not recorded
(Gupta et al., 2012)	PCS	University	20	40	2(2)	Custome made (Denticon, Mumbai)	1.4	8	Stability	22.5	Not recorded
(Sar et al., 2013)	PCS	University	28	28	2(2)	Stryker, Leibinger, Germany	2	8	Not recorded	Not recorded	Not recorded
(Yoo et al., 2014)	PSC	University	132	227	Not recorded	Biomaterial Korea	1.5	7	Stability/ Problems in loading	19.5	Not recorded
(Khanna et al., 2014)	PCS	University	25	100	Not recorded	S.K. Surgical Pvt. Ltd.	1.3	9	Not recorded	Not recorded	Not recorded
(Sandler et al., 2014)	RCT	Hospital	71	44	2(2)	American Orthodontics	1.6	8	Not recorded	2.8%	Not recorded
(Falkensammer et al., 2014)	RCT	University	26	Not recorded	Not recorded	Dual Top G2 8x6mm, Jeil Medical Corporation, Seoul, Korea) it is different in website	1.6	8	Not recorded	NR	Not recorded

Author	Design	Setting	Number of patients	Number of miniscrews		Type of miniscrews	Dimensions		Success criteria	Failure rate (%)	Handling of failure
				Total	Per patient (per Jaw)		Diameter (mm)	Length (mm)			
(Al-Sibaie and Hajeer, 2014)	RCT	University	30	56		Dewimed®, Tuttlingen, Germany	1.6	7	Stability	5%	Replaced
(Sharma et al., 2012)	RCT	University	46	30	2(2)	Denticon	1.2	8	Stability	3%	Replaced
(Davoody et al., 2013)	PCS	University	25	26	2(2)	NR	1.8-2	8-9	Not recorded	16%	Replaced
(Bechtold et al., 2013)	RCT	University	30	76	1 or 2 depend on the intervention	Orlus 18107, Ortholution	1.8	7	Not recorded	13.4%	Replaced
(Ma et al., 2008)	RCT	University		60	4(2)	AbsoAnchor (Dentos,Daegu,Korea)/Dual-Top (Jeil Medical,Seoul,Korea)	1.8	5 mandible 6 maxilla	Not recorded	Not recorded	Not recorded

RCT* Randomised clinical trial

CCt** Controlled clinical trial

PCS*** Prospective cohort study

Table 4 Excluded studies

Article	Reason for exclusion
Are orthodontic distalizers reinforced with the temporary skeletal anchorage devices effective?(Fudalej and Antoszewska, 2011)	Review article
Immediate versus conventional loading of palatal implants in humans: a first report of a multicenter RCT(Jung et al., 2011)	Not relevant
Predictors of initial stability of orthodontic miniscrew implants(Lim et al., 2011)	Retrospective study
Maxillary canine retraction with self-ligating and conventional brackets: A randomized clinical trial(Mezomo et al., 2011)	Not relevant
A new methodological and clinical approach for the treatment of upper lateral incisors agenesis: The posterior space opening(Favero et al., 2012)	Not relevant
Reliability of computer designed surgical guides in six implant rehabilitations with two years follow-up(Giordano et al., 2012)	Not relevant
Success of miniscrews used as anchorage for orthodontic treatment: Analysis of different factors(Giuliano Maino et al., 2012)	Retrospective study
The effect of Teflon coating on the resistance to sliding of orthodontic archwires(Farronato et al., 2012)	In vitro
Moderate to severe anterior open-bite cases treated using zygomatic anchorage(Ileri et al., 2012)	Unsupported opinion of expert
A comparison of space closure rates between preactivated nickel-titanium and titanium-molybdenum alloy T-loops: A randomized controlled clinical trial(Keng et al., 2012)	Not relevant
Anchorage loss during canine retraction using intermittent versus continuous force distractions; a split mouth randomized clinical trial(Mowafy and Zaher, 2012)	Not relevant

Article	Reason for exclusion
Distal movement of upper permanent molars using midpalatal mini-implant(de Lira et al., 2013)	In vitro
Distalization of maxillary molars using a lever arm and mini-implant(Gurgel Jde et al., 2013)	Unsupported opinion of expert
Direct versus indirect loading of orthodontic miniscrew implants-an FEM analysis(Holberg et al., 2013)	Unsupported opinion of expert
A novel anchorage technique for transnasal traction in rigid external maxillary distraction(Varol and Basa, 2013)	Not relevant
Canine retraction: A randomised clinical trial comparing Damon™ 3 self-ligating with conventional ligating brackets	Not relevant
The effect of drilling speed on early bone healing to oral implants(Yeniyol et al., 2013)	Animal study
Reinforcement of anchorage during orthodontic brace treatment with implants or other surgical methods(Jambi et al., 2014)	Cochrane review
Implants for orthodontic anchorage: Success rates and reasons of failures(Rodriguez et al., 2014)	Systematic review
Comparison of anchorage reinforcement with temporary anchorage devices or a Herbst appliance during lingual orthodontic protraction of mandibular molars without maxillary counterbalance extraction(Metzner et al., 2015)	Retrospective study
Machine-driven versus manual insertion mode: influence on primary stability of orthodontic mini-implants(Novsak et al., 2015)	In vitro
Comparison of two maxillary protraction protocols: tooth-borne versus bone-anchored protraction facemask treatment(Ngan et al., 2015)	Retrospective study
Are orthodontic distalizers reinforced with the temporary skeletal anchorage devices effective?(Fudalej and Antoszewska, 2011)	Review article
Immediate versus conventional loading of palatal implants in humans: a first report of a multicenter RCT(Jung et al., 2011)	Not relevant
Predictors of initial stability of orthodontic miniscrew implants(Lim et al., 2011)	Retrospective study

Article	Reason for exclusion
Maxillary canine retraction with self-ligating and conventional brackets: A randomized clinical trial(Mezomo et al., 2011)	Not relevant
A new methodological and clinical approach for the treatment of upper lateral incisors agenesis: The posterior space opening(Favero et al., 2012)	Not relevant
Reliability of computer designed surgical guides in six implant rehabilitations with two years follow-up(Giordano et al., 2012)	Not relevant
Success of miniscrews used as anchorage for orthodontic treatment: Analysis of different factors(Giuliano Maino et al., 2012)	Retrospective study
The effect of Teflon coating on the resistance to sliding of orthodontic archwires(Farronato et al., 2012)	In vitro
Moderate to severe anterior open-bite cases treated using zygomatic anchorage(Ileri et al., 2012)	Unsupported opinion of expert
A comparison of space closure rates between preactivated nickel-titanium and titanium-molybdenum alloy T-loops: A randomized controlled clinical trial(Keng et al., 2012)	Not relevant
Anchorage loss during canine retraction using intermittent versus continuous force distractions; a split mouth randomized clinical trial(Mowafy and Zaher, 2012)	Not relevant
Distal movement of upper permanent molars using midpalatal mini-implant(de Lira et al., 2013)	In vitro
Distalization of maxillary molars using a lever arm and mini-implant(Gurgel Jde et al., 2013)	Unsupported opinion of expert
Direct versus indirect loading of orthodontic miniscrew implants-an FEM analysis(Holberg et al., 2013)	Unsupported opinion of expert
A novel anchorage technique for transnasal traction in rigid external maxillary distraction(Varol and Basa, 2013)	Not relevant

Article	Reason for exclusion
Canine retraction: A randomised clinical trial comparing Damon™ 3 self-ligating with conventional ligating brackets	Not relevant
The effect of drilling speed on early bone healing to oral implants(Yeniyol et al., 2013)	Animal study
Reinforcement of anchorage during orthodontic brace treatment with implants or other surgical methods(Jambi et al., 2014)	Cochrane review
Implants for orthodontic anchorage: Success rates and reasons of failures(Rodriguez et al., 2014)	Systematic review
Success rate and risk factors associated with mini-implants reinstalled in the maxilla (Baek et al., 2008)	Retrospective study
Comparison of anchorage reinforcement with temporary anchorage devices or a Herbst appliance during lingual orthodontic protraction of mandibular molars without maxillary counterbalance extraction(Metzner et al., 2015)	Retrospective study
Machine-driven versus manual insertion mode: influence on primary stability of orthodontic mini-implants(Novsak et al., 2015)	In vitro
Midpalatal miniscrews for orthodontic anchorage: factors affecting clinical success (Kim et al., 2010b)	Retrospective study
Do miniscrews remain stationary under orthodontic forces ? (Liou et al., 2004)	Retrospective study
Treatment effects and anchorage potential of sliding mechanics with titanium screws compared with the Tweed-Merrifield technique (Park et al., 2008)	Retrospective study
Factors associated with the success rate of orthodontic miniscrews placed in the upper and lower posterior buccal region. (Moon et al., 2008)	Retrospective study
Comparison of two maxillary protraction protocols: tooth-borne versus bone-anchored protraction facemask treatment(Ngan et al., 2015)	Retrospective study
Survival analyses of surgical; miniscrews as orthodontic anchorage(Viwattanatipa et al., 2009)	Retrospective study
Clinical outcome of miniscrews used as orthodontic anchorage.(Justens and De Bruyn, 2008)	Retrospective study

Table 5 Risk of bias assessment of the included clinical trials

Author	Year	Study type	Random sequence generation	Allocation concealment	Blinding of outcome assessors	Incomplete outcome data	Selective reporting	Other bias	Overall risk of bias
Sharma et al	2012	RCT	Yes	Yes	Yes	Yes	Yes	Yes	Low risk
Chaddad et al	2008	CCT	No	No	No	Yes	Unclear	No	High risk
Garfinkle et al	2008	RCT	Unclear	Unclear	No	Yes	Unclear	No	High Risk
Aboul-Ela et al	2011	RCT	Yes	Unclear	No	Yes	Unclear	No	High Risk
Liu et al	2009	RCT	Yes	Unclear	No	Yes	Unclear	No	High Risk
Lehnen et al	2011	RCT	Unclear	Unclear	Yes	Yes	Unclear	Yes	High Risk

Author	Year	Study type	Random sequence generation	Allocation concealment	Blinding of outcome assessors	Incomplete outcome data	Selective reporting	Other bias	Overall risk of bias
Sandler et al	2014	RCT	Yes	Yes	Yes	Yes	Yes	No	Low Risk
Turkoz et al	2010	RCT	Unclear	Unclear	No	Yes	Unclear	No	High Risk
wiechmann et al	2007	RCT	Unclear	Unclear	No	Yes	Unclear	Yes	High Risk
Upadhyay et al	2008	RCT	Yes	Yes	Unclear	Yes	Unclear	Yes	Unclear
Alsibaie & Hajeer	2014	RCT	Yes	Yes	Yes	Yes	Yes	Yes	Low risk
Falkensammer et al	2014	RCT	Yes	Yes	Yes	Yes	Unclear	Yes	Low risk
Upadhyay et al	2008 (B)	CCT	No	No	No	Yes	Unclear	Yes	High risk
Basha et al	2010	CCT	No	No	No	Yes	Unclear	Yes	High risk

Author	Year	Study type	Random sequence generation	Allocation concealment	Blinding of outcome assessors	Incomplete outcome data	Selective reporting	Other bias	Overall risk of bias
Ma et al.	2008	RCT	Yes	Unclear	Yes	Yes	Unclear	No	High risk
Bechtold	2013	RCT	Yes	Unclear	No	Yes	Unclear	No	High risk

Table 6 Risk of bias assessment of included cohort studies using Newcastle-Ottawa Scale (NOS)

		Selection				Comparability	Outcome				
Study	**Year**	**Representativeness of exposed cohort**	**Selection of non-exposed cohort**	**Ascertainment of exposure**	**Demonstration that outcome of interest was not present at the start of the study**	**Comparability of the cohorts**	**Assessment of outcome**	**Was follow-up long enough ?**	**Adequacy of follow up**	**NOS score**	**Overall assessment**
El-Beialy et	**2009**	**0**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**5**	**Medium**
Motoyoshi et al	**2009**	**1**	**0**	**1**	**1**	**0**	**0**	**1**	**1**	**5**	**Medium**
Motoyoshi et al	**2007**	**1**	**0**	**1**	**1**	**0**	**0**	**1**	**1**	**5**	**Medium**
Motoyoshi et al	**2010 a**	**1**	**0**	**1**	**1**	**0**	**0**	**1**	**1**	**5**	**Medium**
Cheng et al	**2004**	**1**	**0**	**1**	**1**	**0**	**0**	**1**	**1**	**5**	**Medium**
Motoyoshi et al	**2010 b**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**
Alves et al	**2011**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**
Gelgor et al	**2004**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**
Hedayati	**2007**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**
Herman et al	**2006**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**

		Selection				Comparability	Outcome				
Study	**Year**	**Representativeness of exposed cohort**	**Selection of non-exposed cohort**	**Ascertainment of exposure**	**Demonstration that outcome of interest was not present at the start of the study**	**Comparability of the cohorts**	**Assessment of outcome**	**Was follow-up long enough?**	**Adequacy of follow up**	**NOS score**	**Overall assessment**
Kim et al	**2010**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**
Miyazawa et al	**2010**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**
Motoyoshi et al	**2006**	**1**	**0**	**1**	**1**	**0**	**0**	**1**	**1**	**5**	**Medium**
Blaya et al	**2010**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**
Thiruvenkatachari et al	**2006**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**
Bayat & Bauss	**2010**	**0**	**1**	**1**	**1**	**1(maximum score is 2**	**0**	**0**	**1**	**5**	**Medium**
Luzi et al	**2007**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**
Polat-Ozsoky et al	**2009**	**1**	**0**	**1**	**0**	**0**	**0**	**0**	**1**	**3**	**Low**
Yoo et al	**2014**	**0**	**0**	**1**	**1**	**1(maximum score is 2**	**1**	**1**	**1**	**6**	**Medium**

		Selection				Comparability	Outcome				
Study	**Year**	**Representativeness of exposed cohort**	**Selection of non-exposed cohort**	**Ascertainment of exposure**	**Demonstration that outcome of interest was not present at the start of the study**	**Comparability of the cohorts**	**Assessment of outcome**	**Was follow-up long enough?**	**Adequacy of follow up**	**NOS score**	**Overall assessment**
Khanna et al	**2014**	**1**	**0**	**1**	**1**	**0**	**0**	**1**	**0**	**4**	**Medium**
Sar et al	**2013**	**1**	**0**	**1**	**1**	**0**	**0**	**1**	**1**	**6**	**Medium**
Gupta and Kotrashetti	**2012**	**1**	**1**	**1**	**1**	**0**	**0**	**1**	**1**	**6**	**Medium**
Apel et al	**2009**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**
Berens et al	**2014**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**
Davoody et al	**2012**	**1**	**1**	**1**	**1**	**1**	**0**	**1**	**1**	**7**	**High**
Upadhyay	**2009**	**1**	**0**	**1**	**1**	**0**	**1**	**1**	**1**	**6**	**Medium**
Upadhyay	**2012**	**1**	**0**	**1**	**1**	**1**	**1**	**1**	**1**	**7**	**High**

3.3.5 Miniscrews failure rate.

2838 miniscrews extracted from 38 studies were pooled in a random-effect model. The failure rate was 14.1% (95% CI, 12-16.5, Q=86.34, P= 0.000, I^2= 57.1%) as shown in Figure 14.

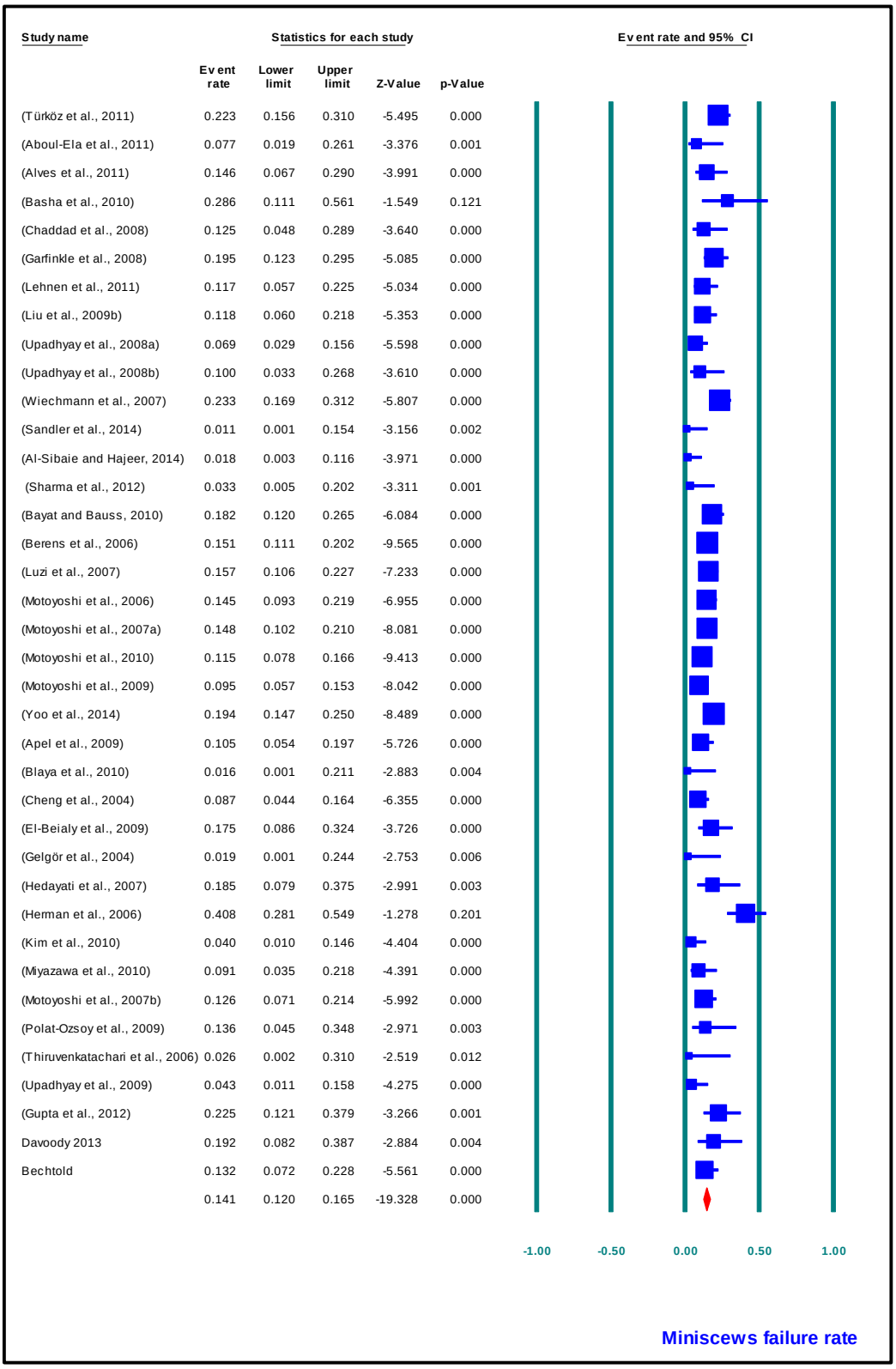


Figure 14 Forest plot of overall miniscrews failure rate (random-effect model

3.3.6 Subgroup analysis

3.3.6.1 Diameter

Data of 2503 miniscrews were extracted from 36 studies and pooled in a random-effect model (Figure 15). In this model, the miniscrews were grouped according to diameter; small if diameter was up to 1.3; medium if diameter was 1.4-1.6 and large if diameter was 1.7-2. The failure rate of 450 miniscrews which had small diameter was 10.7% (95% CI, 7.6-15, Q=14.15, DF=11, P=0.255, I^2= 22.26 %). In 1586 miniscrews which had medium diameter, the failure rate was 15.3 % (95% CI, 12.3-18.8, Q= 41.33, DF= 16, P=0.000, I^2= 61.2%). In 391 miniscrews which had large diameter, the failure rate14.4% (95% CI, 8.4-23.5, Q=34.2, DF=9, P=0.000, I^2=73.6%).

3.3.6.2 Length

32 studies reported on the length of 2213 miniscrews. 88 % (1943) were shorter than or equal to 8 mm and 12 % (273) longer than 8mm. The failure rate of the short miniscrews was 13.4 % (95% CI, 11.2-16.0, Q=47.26, P=0.007, DF=26, I2=44.9%) while the failure rate for long miniscrews was 8.3% (95% CI, 3.1-20.2, Q=15.2, DF=5, P= 0.009, I2=67.2%) as shown in Figure 16.

3.3.6.3 Design.

16 studies included 823 miniscrews showed comparable failure rate of self-drill miniscrews (18.2%, 95% 6.4-41.9, Q= 51.57, DF=6, P=0.000, I^2=88.36%) and non-self-drill miniscrews (18.5%, 95% CI, 13.7-24.5, Q=20.7, DF= 8, P=0.008, I^2=61.5%) as shown in Figure 17.

3.3.6.4 Age

Data of 693 of miniscrews were extracted from 11 studies reported on patients' age. 457(66%) miniscrews were placed in young patients (≤18 years) and 236 (34%) miniscrews were in adult patients (> 18 years). Failure rate of miniscrews placed in young patients was 8.6% (95% CI, 4.7-15.1, Q=20.87, DF= 7, P=0.004. $I^{2=}$66.47%) and 14.2% (95% CI, 10.2-19.3, Q=.0924, DF=2, P= 630, I^2=0%) in adult patients as shown in Figure 18.

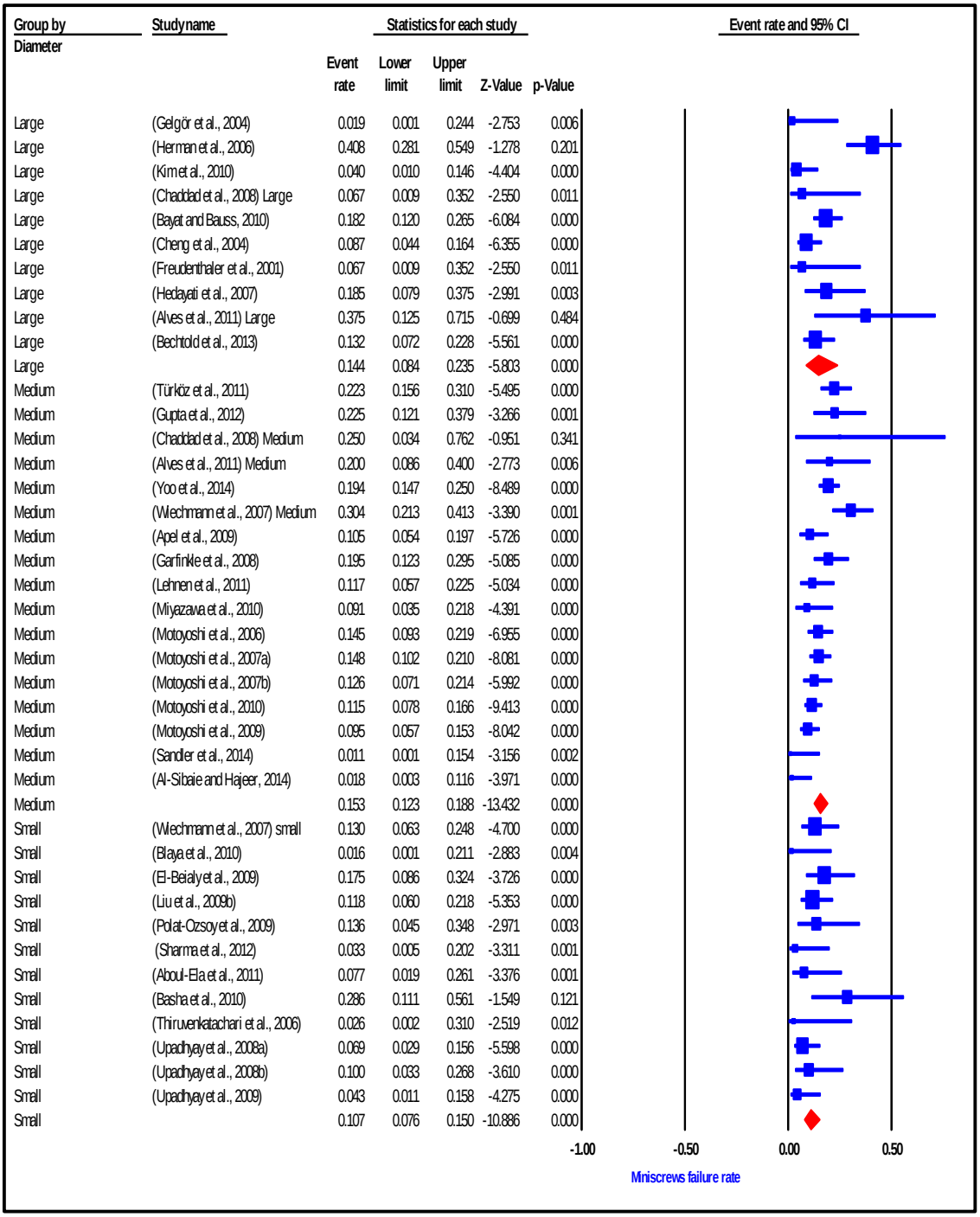


Figure 15 Forest plot of failure rate of miniscrews with different diameters (random-effect model)

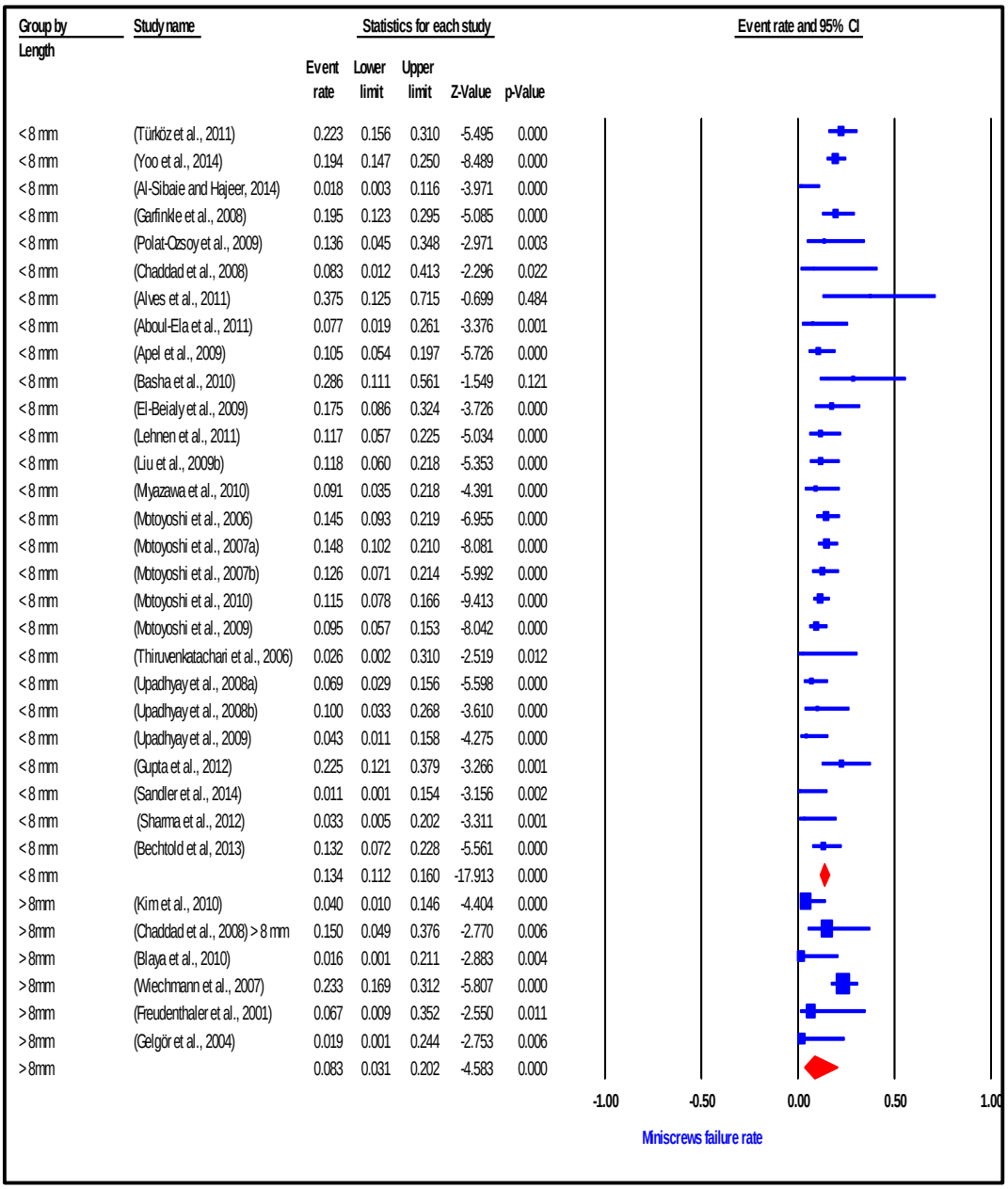


Figure 16 Forest plot of failure rate of miniscrews with different lengths (random-effect model)

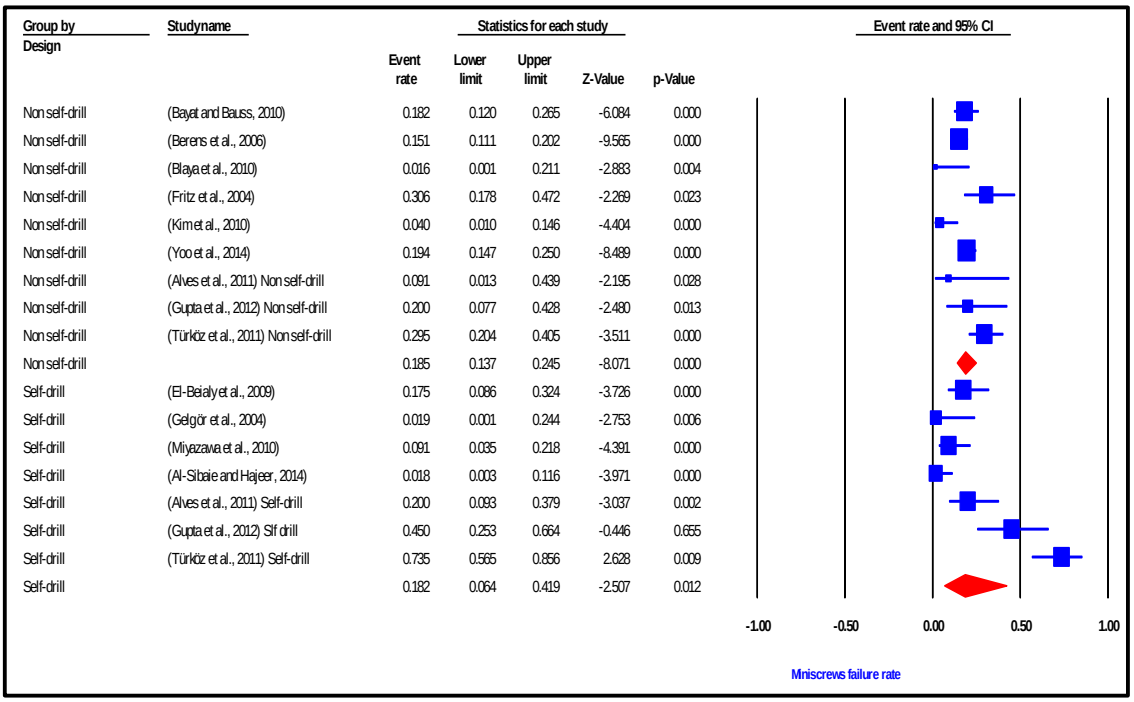


Figure 17 Forest plot of failure rate of miniscrews with different designs (random-effect models)

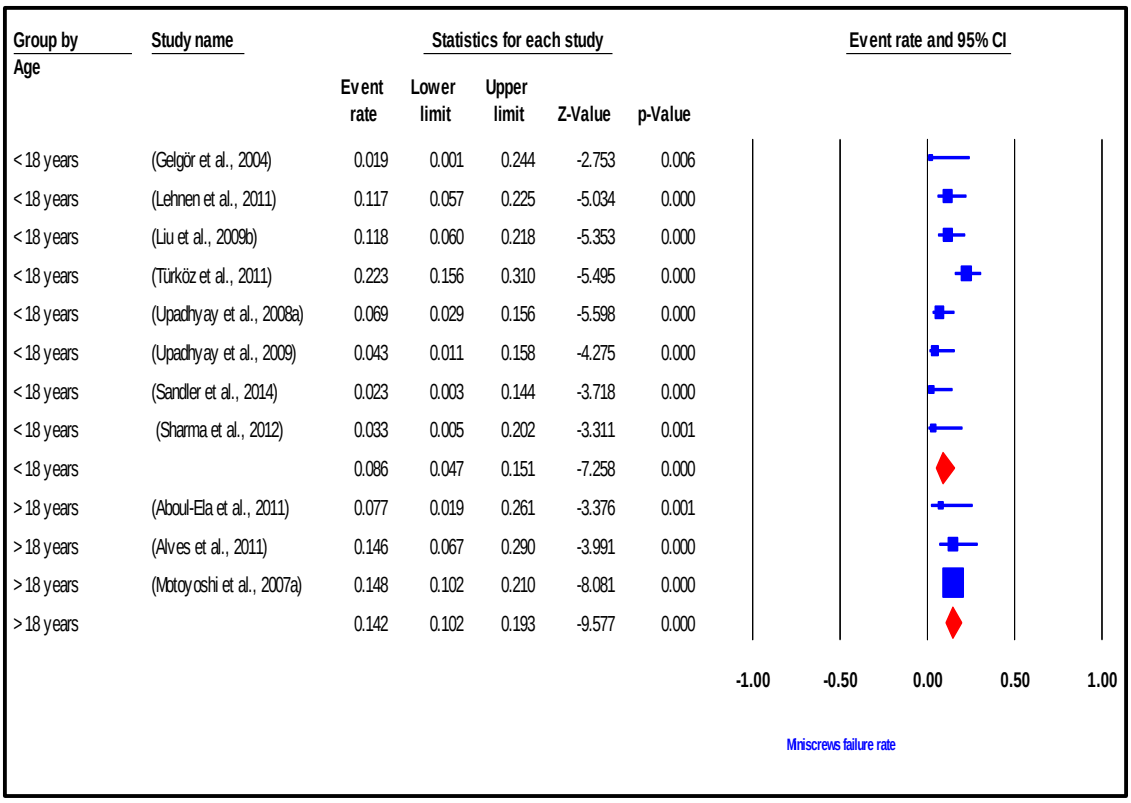


Figure 18 Forest plot of failure rate of miniscrews with different age groups (random-effect model)

3.3.6.5 Jaw.

17 studies reported on miniscrews placed in maxilla or mandible. Data of 1970 miniscrews were pooled into a random-effect model. 71% (1404) were placed in the maxilla and 29% (566) were placed in the mandible. The failure rate was 12.2% (95% CI, 9.9-14.9, Q = 61.5, DF=26, P= 0.002, I^2= 63.4%) and 15.5% (95% CI, 10.6-22.1, Q = 30.120, DF=11, P= 0.002, I^2= 63.4%) for the maxilla and mandible respectively as shown in Figure 19.

3.3.6.6 Smoking.

Only one study (Bayat and Bauss, 2010) evaluated the association between smoking and miniscrews failure rate. 110 miniscrews in total were included in this study with 20 miniscrews failed. Seven miniscrews out of 73 (9.5%) were placed in non-smokers (≤ 10 cigarettes/day). Two out of 18 miniscrews placed in light smokers failed (11%) while the failure rate was 57.8% (11 out of 19 miniscrews) in heavy smokers (≥ 10 cigarettes/day).

3.3.6.7 Types of mucosa (keratinized tissue or not)

Only Chaddad et al (2008) reported on the effect of placing miniscrews in keratinized tissue. 32 miniscrews were included in the study with 11 of them were placed in keratinized tissue with no failure and 21 miniscrews placed in non-keratinized tissue with 4 failed miniscrews (19%).

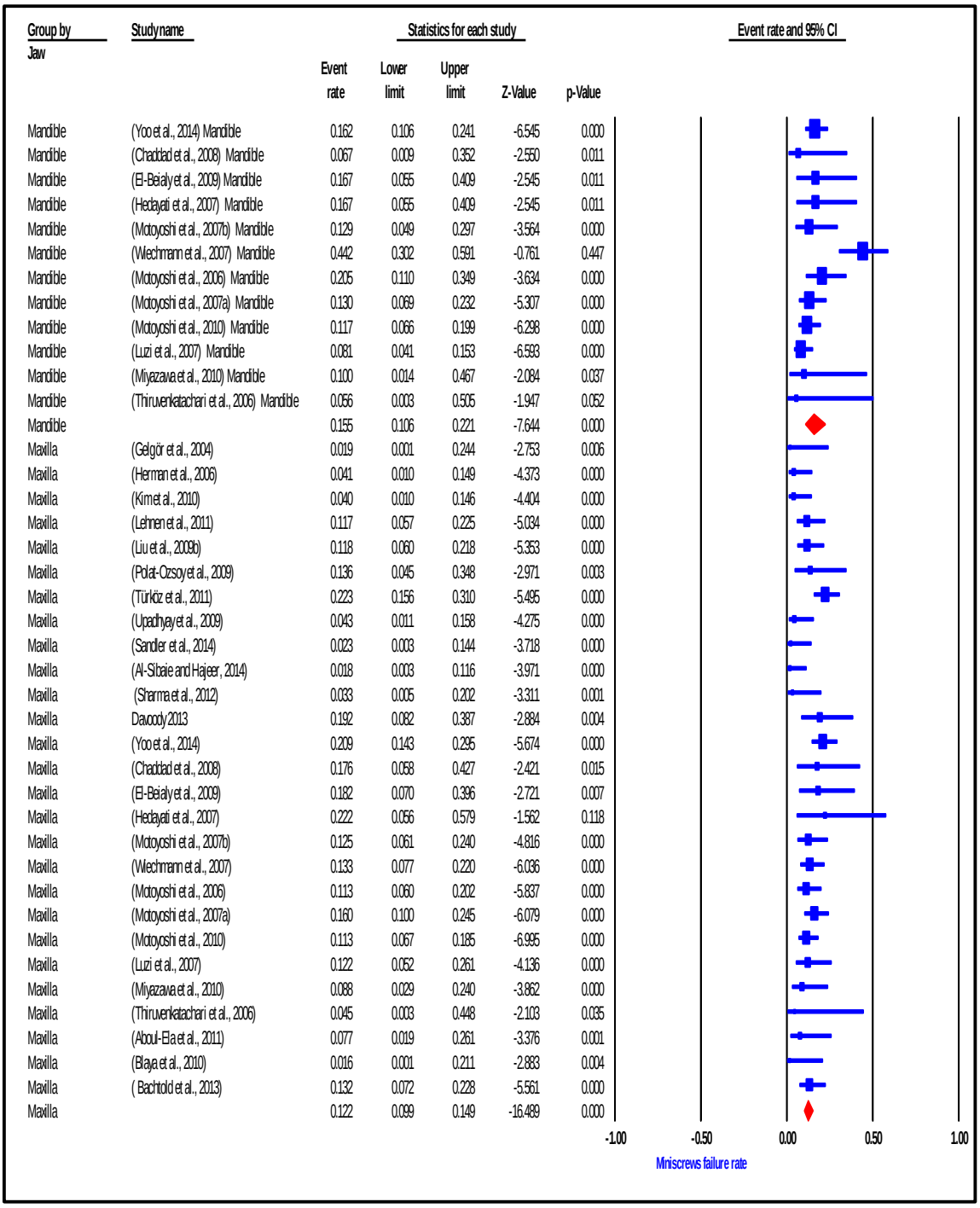


Figure 19 Forest plot of failure rate of miniscrews according to jaw (random-effect model)

Table 7 Summary of miniscrews failure rates with associated factors

Factor	Number of studies	Included miniscrews	Failure rate	95% CI	Heterogeneity (I^2%)
Diameter (mm)					
Small (Up to 1.3 mm)	9	450	10.7 %	7.6-15	22.26 %
Medium (1.4-1.6 mm)	17	1586	15.3%	12.3-18.8	61.2%
Large (1.7-2 mm)	12	391	14.3%	7.7-25.1	75.6%
Length (mm)					
Short (< 8mm)	26	1867	13.4 %	11.1-16.1	46.9%
Long (>8mm)	6	273	8.3%	3.1-20.2	67.2%
Design					
Self-drilling	9	249	18.2%	6.4-41.9	88.36%
Non self-drilling	7	574	18.5%	13.7-24.5	61.5%
Age					
Younger than 18 years	8	457	8.6%	4.7-15.7	66.47%
Older than 18 years	3	236	14.2%	10.2-19.3	0%
Jaw					
Maxilla	26	1328	12%	9.8-16.4	59.3%
Mandible	12	566	15.5%	10.6-22.1	63.4%
Smoking					
Non-smokers	1	73	9.5%	Not reported	Not reported
Light smokers	1	18	11%		
Heavy smokers	1	19	57.8%		
Kind of mucosa					
Keratinized	1	11	0%	Not reported	Not reported
Non-keratinized	1	21	19%		

3.3.7 Sensitivity analysis.

3.3.7.1 Miniscrews number.

Data of 1227 miniscrews extracted from 28 studies that included a total number of miniscrews less than 100 for each study were pooled in a random-effect model. The failure rate of 12% (95% CI, 9.3-15.5, Q=64.9, DF= 27, P=0.000, I^2=58.4%) was not strongly different from the summary points estimates of the effect size of all the studies as shown in Figure 20.

Data from 10 studies where each study included more than 100 miniscrews were analysed in a random-effect model. The total number of miniscrews placed was 1611. The failure rate was 16.2 %(95%CI, 13.8-19.1, 18.76, DF=9, P=0.027, I^2=27.02%). Similarly, in studies where more than 100 miniscrews were placed, the rate did not differ dramatically from the estimates of the effect size of the main analysis.

3.3.7.2 Study design

15 clinical trials that included 876 miniscrews were pooled in one random-effect model as a part of the sensitivity analysis. Their failure rate was 13.5 % (95% CI, 10.1-17.9, Q=31.5, DF=14, P=0.005, I^2=55.6%).The number of cohort studies included in this meta-analysis were 23 including 2038 miniscrews. The failure rate of included miniscrews in cohort studies was 14.3 %(95% CI, 11.7-17.2, Q=54.1, DF=22, P=0.000, I^2= 59.42%) as shown in Figure 21.

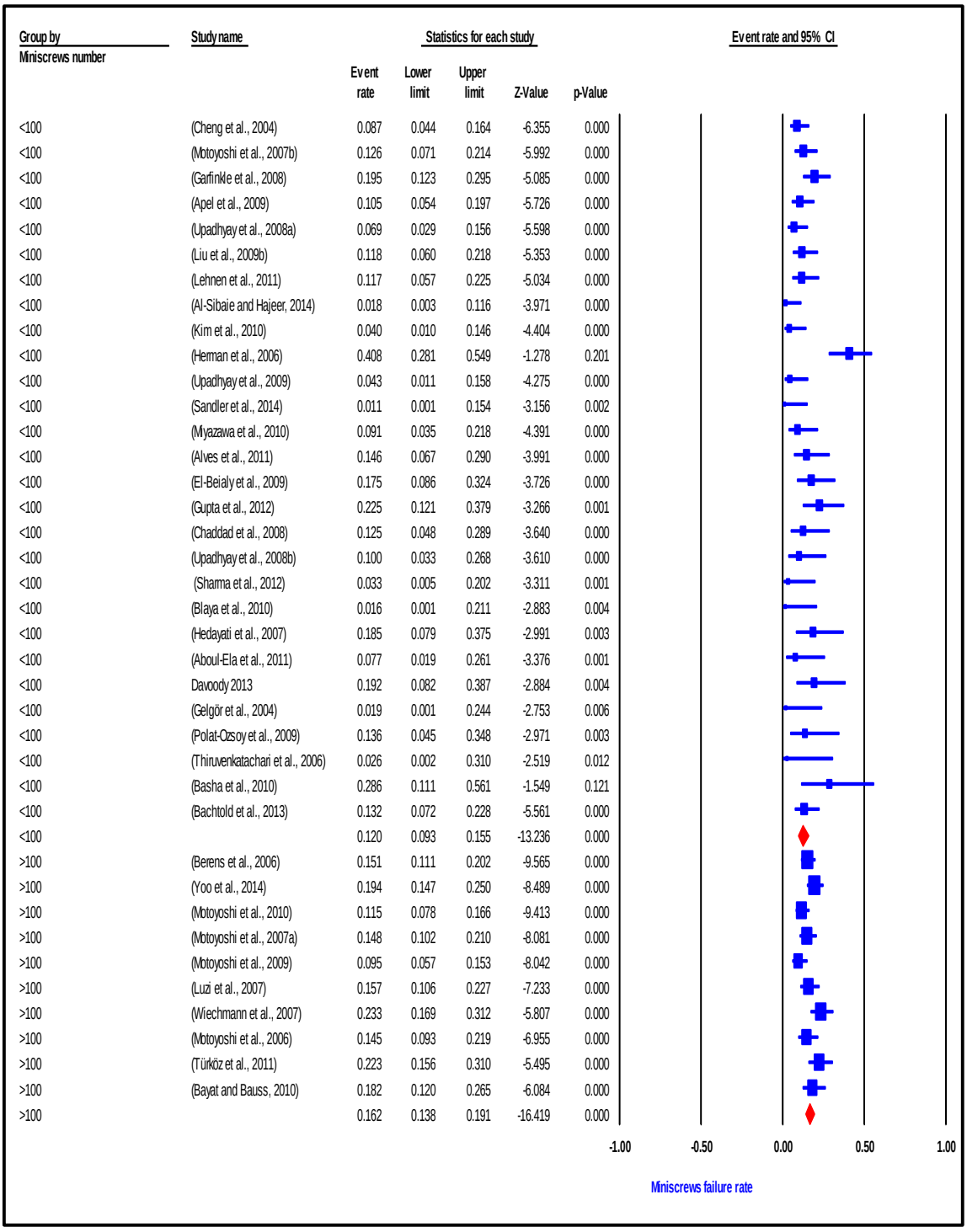


Figure 20 Forest plot of failure rate of miniscrews according to number of included miniscrews per study (random-model effect)

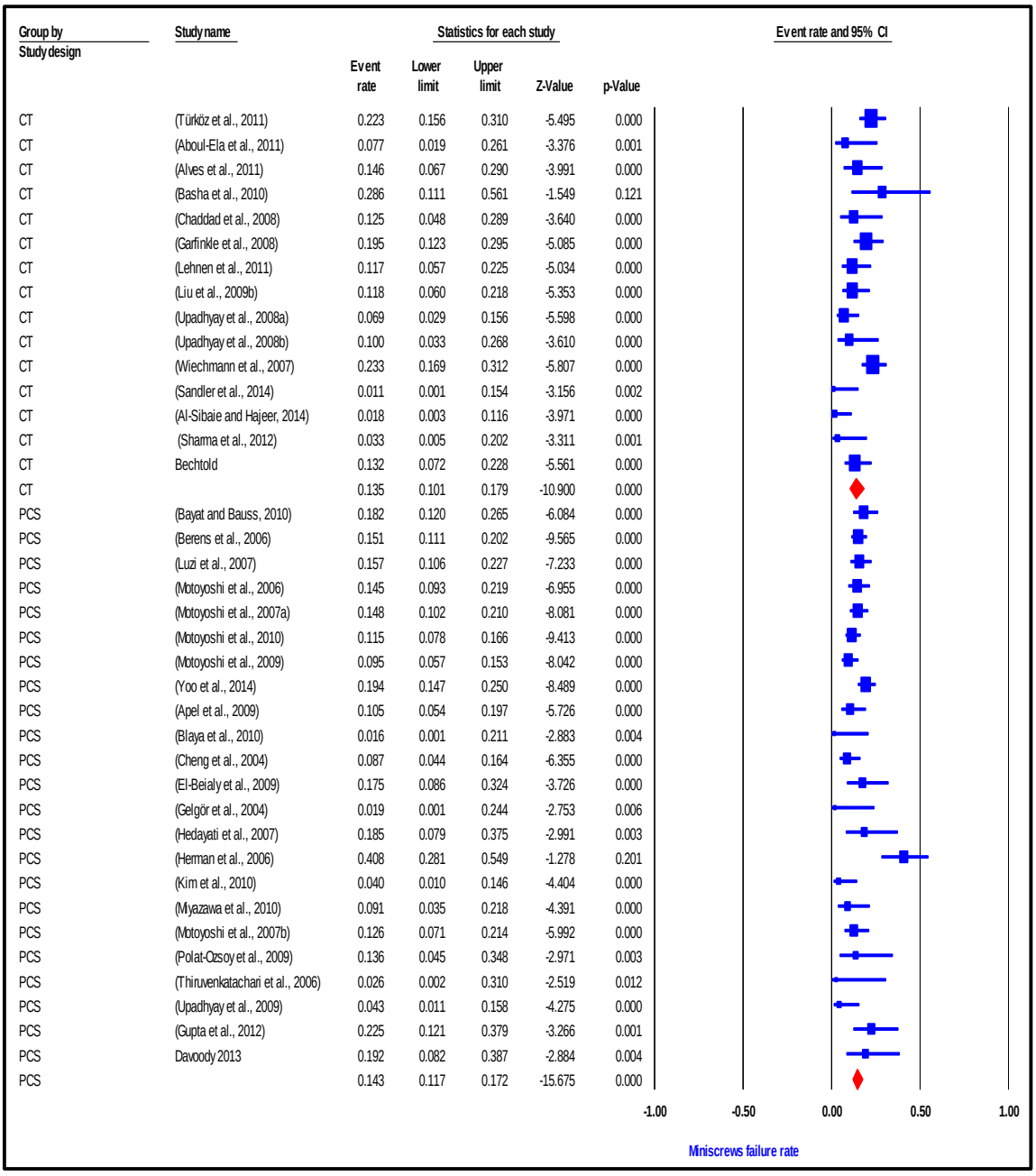


Figure 21 Forest plot of miniscrews failure rate based on the design of included study (random-effect model)

3.3.8 Publication bias analysis

Figure 22 shows a funnel plot for 38 studies where the effect sizes were plotted against standard error. The vertical line represents the weighted mean effect size estimate. As one would expect, studies with a smaller sample size and large sampling error would scatter toward the bottom of the funnel plot. If the publication bias is not present, the data points will be distributed symmetrically around the mean effect size estimate. In this current meta-analysis, the shape of the inverted funnel-plot was asymmetrical between the right and the left sides of the plot meaning that there was absence of smaller sized studies towards the right side of the plot. Therefore a considerable publication bias due to a failure of including studies with small effect sizes seems likely in this meta-analysis.

Furthermore, both Begg's test (Kendall's tua=-0.34535. P= .00131) and Egger's test (-1.789, 95% CI, -2.70- -0.874, P=0.00017) suggested that publication bias is likely present in this meta-analysis.

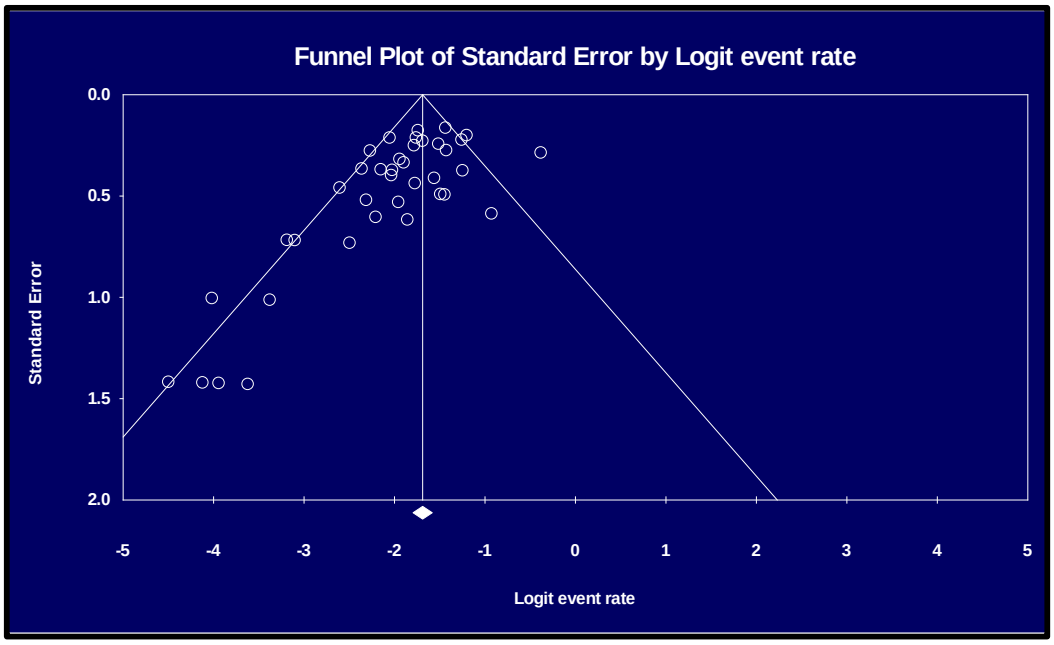


Figure 22 Funnel plot of 38 studies included in the meta-analysis

3.4 Discussion

This systematic review included 16 clinical trials and 27 prospective cohort studies. 3130 miniscrews were placed in 1605 patients in all included studies. Most of these miniscrews were used to reinforce orthodontic anchorage. The majority of the included clinical trials were judged as having a high risk of bias. In most of these trials, randomisation and allocation concealment procedures were either inadequate or reported incompletely. The quality of most of prospective cohort studies was medium. This can be attributed to the fact that most of included cohort studies did not include a comparison group, thus, they had a lower score in the Newcastle-Ottawa Scale.

The meta-analysis estimated the miniscrews failure rate to be 14.1% (95% CI, 12-16.5). This finding differed slightly from the failure rate previously reported by Papageorgiou et al. (2012) who found that the failure rate to be 13.5 %(95% CI, 11.5-15.8). The difference between the two estimates might have resulted from including recent studies in our meta-analysis (Yoo et al., 2014; Khanna et al., 2014b; Falkensammer et al., 2014; Al-Sibaie and Hajeer, 2014; Davoody et al., 2013; Bechtold et al., 2013; Gupta et al., 2012; Sandler et al., 2014; Sar et al., 2013). Secondly, we excluded retrospective studies, studies with unclear design and studies in language other than English that had been included in their meta-analysis (Freudenthaler et al., 2001; Fritz et al., 2004; Liou et al., 2004; Gelgor et al., 2007; Kuroda et al., 2007b; Baek et al., 2008; Kim et al., 2010c; Lee et al., 2010; Maddalone et al., 2010; Oh et al., 2011; Park et al., 2006a; Park et al., 2008; Suzuki and Suzuki, 2011; Wang et al., 2009a; Wang et al., 2009b; Wilmes et al., 2009; Wu et al., 2009).

The estimate of failure rate in this meta-analysis was similar to the estimate of recent systematic review and meta-analysis of miniscrews with diameter up to 2.5 mm (Beltrami et al., 2015). The authors found the success rate to be 86.75% and the corresponding failure 13.25%. However, despite the similar failure rate to ours and Papageorgiou et al (2012) estimates, their systematic review suffered from obvious flaws as they included retrospective studies which increased the risk of bias. Moreover, the researchers did not include studies that were published after 2010.

Associated factors with miniscrew failure were assessed in subgroup analyses. Miniscrews diameter and length were reported in more studies than any other factor except for the location (maxilla or mandible).

It appeared from the findings of this meta-analysis that miniscrews with diameter smaller than 1.3 mm had a lower failure rate (10.5%, 95% CI, 7.6-15) when compared with miniscrews with diameter of 1.4-1.6 mm (15.3%, 95% CI, 12.3-18.8) and diameter of 1.7-2 mm (14.3%, 95% ci, 7.7-25.1). However, the number of included miniscrews with small diameter was 450 while the included miniscrews with medium diameter were 1586 and the ones with large diameter were 391. This variation in sample size between the included miniscrews and the variation in heterogeneity may have influenced the findings. Papageorgiou et al (2012) found comparable failure rates for miniscrews of small and large diameter: 10.9 %(95% CI, 7.7-15.3) and 14.3 %(95% CI, 7.4-25.8) respectively. However, they found that miniscrews with medium diameter had failure rate of 12.7% (95% CI, 8.1-19.3). Lime et al. conducted two retrospective studies and found that the miniscrew diameter had no significant effect on their success (Lim et al., 2011; Lim et al., 2009).

The miniscrews in this meta-analysis were divided into short (≤ 8mm) and long (> 8mm). The failure rate of short miniscrews was 13.4 % (95% CI, 11.1-16.9) while the failure rate for long miniscrews was 8.3% (95% CI, 3.1-20.2).The reason why we did not follow Papageorgiou et al to divide the miniscrews to three groups according to their length was the number of long miniscrews. One reason longer miniscrews have lower failure rate is because they offer better mechanical retention in the bone. But longer miniscrews might be associated with higher risk for injury to surrounding anatomical structures. Nonetheless, the number of short miniscrews in our meta-analysis was 1867 while the long miniscrews were only 273. Most of the studies used short miniscrews (Table 7).

The design of the miniscrews was compared in a small number of included studies and did not have any effect on the failure rate according to our findings. The failure rate of self-drilling miniscrews, the design of which enables them to be inserted in the bone without drilling a pilot hole, was18.2 %(95% CI, 6.4-41.9) and for the non-self-drilling was 18.5% (95% CI, 13.7-24.5). Similar finding were reported by

Papageorgiou et al for the non-self-drilling miniscrews where failure rate was 17.7 % (95% CI, 5.1-44.9). Conversely, the failure rate of self-drilling miniscrews was 7.7% (95% CI, 4.8-12.0). We extracted our data about miniscrews design from 9 studies while they extracted their data from 3 studies which may have influenced the estimation of the failure rate. Yi et al (2016) performed a recent systematic review and meta-analysis investigating the effect of the design of miniscrews on their failure rate. They found that the design of miniscrews had no effect on their failure rate.

Most studies recruited a mix of young (≤18 years) and adult patients (>18 years). The failure rate of miniscrews placed in younger patents was 8.6 % (95%, CI, 4.7-15.1) which is lower than the failure rate reported in Papageorgiou et al (2012) who found that the failure rate in patients younger than 20 years was 12.6 (95% CI, 6.4-23.3). The difference between the two estimates could be caused by the variation in the included studies between the two meta-analyses. The failure rate of miniscrews placed in adults according to our analysis was 14.2 % (95% CI, 10.2-19.3) and 15.5 % (95% CI, 11.2-21.0) in Papageorgiou et al. (2012). The two estimates were comparable. In contrary to retrospective studies (Chen et al., 2007, Topouzelis and Tsaousoglou, 2012), older patients had a higher failure rate in this review. Factors including smoking, periodontal disease and miniscrews location might influence failure rate in adult patients. On the other hand, this observation may simply be a function of different sample characteristics of the included studies.

In our analysis the failure rate of miniscrews placed in the maxilla was 12.0 % (95% CI, 9.8-16.4) while the failure rate of those placed in the mandible was 15.5 % (95% CI, 10.6-22.1). Papageorgiou et al (2012) found the failure rate of miniscrews in the maxilla to be 12.0 % (95% CI, 9.6-14.9) which was similar to our findings. However, they found that the failure rate of miniscrews placed in the mandible was 19.3% (95% CI, 14.3-25.6). They extracted the data of miniscrews placed in the mandible from 17 studies while we extracted the data from different 17 studies which has led to different figures. The high failure rate in the mandible can be caused by the greater bone density, the availability of cortical bone around the miniscrews are less, and the narrow vestibule compared with the maxilla (Lim et al., 2009).

Data regarding the effect of smoking on the failure rate of miniscrews was extracted from only one study (Bayat and Bauss, 2010) in our meta-analysis as well as in Papageorgiou et al. (2012). No recent studies have published data on the effect of smoking on miniscrews failure.

The type of mucosa was investigated in only one study (Chaddad et al., 2008). They found that 11 miniscrews placed in the keratinized tissue had no failures. Interestingly, Papageorgiou et al. (2012) found that the failure rate was 12.5% (95% CI, 7.0-21.5) when the miniscrews were placed in keratinized tissue. However, they extracted that data from three studies. The 21 miniscrews placed in non-keratinized tissue had a failure rate of 19% in Chaddad et al study that we included but the standard deviation was not reported. Although many clinicians advise placing miniscrews in keratinized tissue, this advice was based on retrospective studies rather than prospective studies (Chen et al., 2007; Melsen and Verna, 2005).

The above interpretation of the findings should be read with caution due to the significant heterogeneity (Q=86.34, P= 0.000, I^2= 57.1%). between the studies. This is expected because the included studies had different designs, sample sizes and methods. The Papageorgiou et al. (2012) meta-analysis had significant heterogeneity (P<0.001; I^2=74%). Omitting some retrospective studies that had been included in Papageorgiou et al. (2012) meta-analysis may had an effect on reducing the heterogeneity in our meta-analysis. Therefore the estimate of failure rate in this meta-analysis has more confidence.

Sensitivity tests were performed in order to assess whether changes might have an impact on the estimate of the effect size. The failure rate was 16.2% when data were extracted from studies that had included more than 100 miniscrews. This was comparable to the failure rate reported by Papageorgiou et al. (2012) when the data were extracted from studies included more than 100 miniscrews. It is worth mentioning that we included 10 studies with more than 100 miniscrews placed while they included 17 studies. Similarly, after pooling data from clinical trials only in separate random-effect model and then pooling cohort studies in another random-effect model, the failure rate in both models changed slightly from the effect size estimate when all studies were pooled together. It was 13.5 % when data were

extracted from clinical trials only and 14.3% when the data were extracted from cohort studies only.

Inspection of the funnel plot and statistically significant Egger's test and Begg's test suggested that publication bias is likely to be present. This is expected because the included studies in this meta-analysis were retrieved from 4 databases and the included studies were only in English. Additionally, not all studies included in the systematic review were included in the meta-analysis because the authors did not report data on failure rate of miniscrew. Asymmetry in the funnel plot may have been raised not only because of publication bias but also due to true between- study heterogeneity because of different study design and methods or chance (Souza et al., 2007). Additionally, small sample size studies that report on miniscrews failure might exaggerate the failure rate and would be plotted on the right side of point estimate if it was published. For example a study of 10 patients with 2 failures would have 20% failure rate and the study will be plotted to the left side of the funnel plot whereas the rate would 10% if the sample size was 20 patients the study will be plotted to the right side of the funnel plot.

It is worth noting that a funnel plot is able to indicate the presence of the publication bias but it cannot explain the reasons for the asymmetry (Sterne et al., 2011). However, this meta-analysis updated a much broader search performed by Papageorgiou et al. (2012) where they included more sources and they did not have any restriction on language up to February 2011. However, our findings differed only slightly from theirs.

In summary, this meta-analysis provided a 5 years updated on a meta-analysis performed by Papageorgiou et al. (2012). It included 38 studies and thereby provided a better estimation of the failure rate of miniscrews. Including a large number of studies made subgroup analysis possible to assess the factors associated with miniscrews failure rate. However, due to the significant heterogeneity across the studies and possibility of publication bias, those findings should be interpreted with caution.

3.5 Conclusion

- The included studies in this meta analysis were a mix of clinical trials that mostly had a high risk of bias and prospective cohort studies which mostly had moderate quality. Hence, any conclusion should be interpreted with caution
- The failure rate of miniscrews was estimated at 14.1% (95% CI, 12-16.5) which suggests that they are useful clinically.
- Subgroup analysis showed that different factors including miniscrews dimentions, location and patient's age had effect on miniscrew failure. However, the subgroup analysis should be interpted with caution due to high-level heterogeneity and unbalanced groups.

Chapter 4. Anchorage effectiveness of headgear, TPA and Miniscrew: systematic review.

4.1 Introduction

A recent Cochrane review investigated the anchorage effectiveness of two techniques (Jambi et al., 2014). The first technique was surgical anchorage where mid-palatal implants, onplants, zygomatic wires, titanium plates, or miniscrews were used. The second technique was conventional anchorage where headgear, face masks, chin caps, transpalatal arches (including Nance buttons), lingual arches or interarch elastics were used.

Although this was a high quality review, the included studies were not the same focus as this thesis systematic review. The focus of my review will be on finding related studies about miniscrews, high-pull headgear and transpalatal arch. Therefore, I present here a systematic review about the comparative anchorage effectiveness of miniscrews, retraction headgear and transpalatal arch only.

4.2 Methods

4.2.1 Included studies

The included studies in this systematic review were human clinical trials that investigated the orthodontic anchorage reinforcement methods of interest and were published in English. In vitro studies, animal studies, case reports and case series and review articles were excluded. In cases of unclear study design, the author was contacted for further information. Relevant articles were identified first after reading their titles and abstracts. The full text of the potential articles was assessed for eligibility by two reviewers (Fahad Alharbi & David Bearn). In case of disagreement between the two reviewers, a mutual decision was made through open discussion. One reviewer (FA) independently extracted data from the included studies and the following information was included for each study: year of publication, setting, study design, interventions, primary and secondary outcomes.

4.2.2 Types of participants

Patients of any age treated with fixed appliances and anchorage reinforced with miniscrews (diameter ≤ 2mm), retraction headgear or transpalatal arch.

4.2.3 Types of interventions

The treatment group included patients who required anchorage reinforcement by miniscrews with a diameter of 2 mm or less in addition to fixed appliances .The control group included patients treated with retraction headgear or transpalatal arch in addition to fixed appliances.

4.2.3 Types of outcome measures

The primary outcome was the anchorage loss defined as amount of mesial movement of the permanent upper first molar measured in millimetres. Other secondary outcomes including the treatment duration, number of visits, adverse effects and patient experience were collected from the studies where available.

4.2.4 Search methods

The following databases were searched: MEDLINE via Ovid (1946 - March 2016); Cochrane Oral Health Group Trials (searched 2 March 2016); EMBASE via OVID (1980 to March 2016); Scopus searched on March 2, 2016 (Appendix 3).

4.2.5 Assessment of risk of bias in the included studies

Clinical trials were assessed for risk of bias using the Cochrane collaboration's tools by two reviewers (Fahad Alharbi & David Bearn) (Higgins et al., 2011). In case of disagreement between the two reviewers, a mutually agreed decision was made.

4.2.6 Data synthesis and meta-analysis

A meta-analysis was performed using a random-effect model where the included studies had similar characteristics. The heterogeneity across the studies was assessed using the I^2 and Q statistics for heterogeneity. If one of the included studies was a multi-arm study then only single pair-wise comparisons were considered. That means combining all intervention groups into a single group and all control groups into a single group as described in Cochrane Handbook for Systematic Review of Interventions (version 5.1.0)(Higgins and Green, 2008). The statistical tests were

performed using the statistical software Comprehensive Meta-Analysis (Biostat Inc., Englewood, NJ, USA).

4.3 Main results

4.3.1 Results of the search

The search strategy identified 15,469 records. After screening on the basis of title and abstract, 15,436 records were excluded and 33 records were further assessed after the full text had been retrieved (Figure 22). The final sample included 7 randomised clinical trials; six of them were single centre two-arm trials and one was a three-arm trial that was carried out in two centres (Sandler et al., 2014). All of the included studies were conducted in university settings. Three trials were performed in India (Basha et al., 2010; Sharma et al., 2012; Upadhyay et al., 2008) two in China (Liu et al., 2009; Ma et al., 2008) one in Syria (Alsibaie & Hajeer 2014) and one in the UK (Sandler et al., 2014). A total of 282 randomised participants were included in the review.

4.3.2 Characteristics of the participants

In four studies the participants were adolescents (Basha et al., 2010; Sandler et al., 2014; Sharma et al., 2012; Upadhyay 2008) and three studies recruited young adults (Ma et al., 2008; Liu et al., 2009; Alsibaie & Hajeer 2014). More female participants were recruited in four studies (Alsibaie & Hajeer 2014; Sharma et al., 2012; Ma et al., 2008) and one study recruited more males (Sandler et al., 2014). Two studies included only female participants (Basha et al., 2010; Upadhyay et al., 2008).

4.3.3 Characteristics of the interventions

Four studies compared miniscrews to transpalatal arches (TPA) (Basha et al., 2010; Liu et al., 2009; Sharma et al., 2012; Alsibaie & Hajeer 2014) and two compared miniscrews to headgear (HG) (Ma et al., 2008; Sandler et al., 2014). In one study, the comparison was between miniscrews and different methods of conventional anchorage including headgear, TPA, the application of differential moments and the

banding of a second molar (Upadhyay et al., 2008). One study included an additional comparison between miniscrews and Nance, which was a three-arm trial (Sandler et al., 2014).

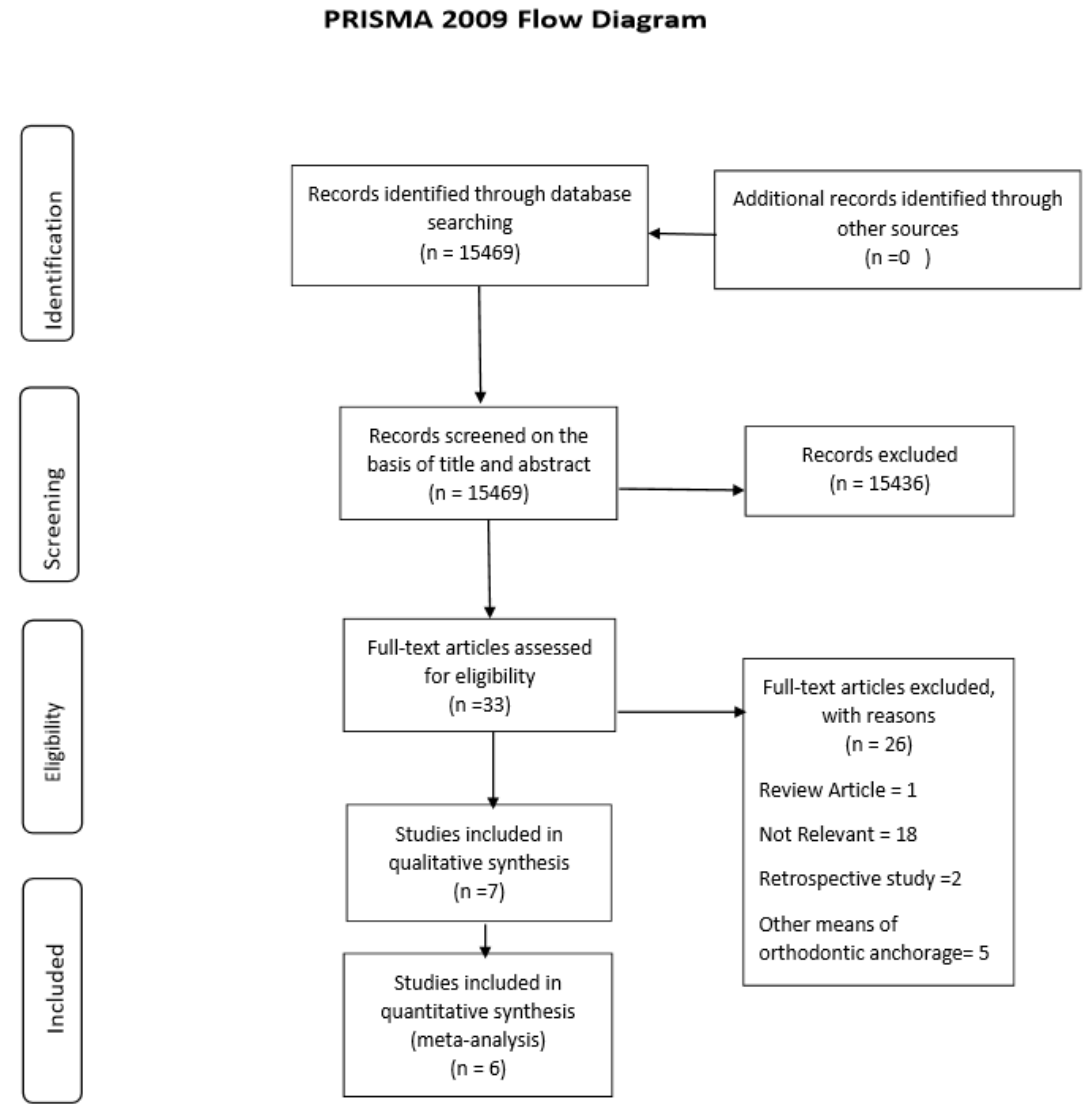


Figure 23 Flow chart of the selection of studies

Table 8 Excluded studies

Article	Reason of exclusion
Maxillary canine retraction with self-ligating and conventional brackets: A randomized clinical trial(Mezomo et al., 2011)	Not relevant
Reinforcement of anchorage during orthodontic brace treatment with implants or other surgical methods(Jambi et al., 2014)	Cochrane review
Success rate of mini- and micro-implants used for orthodontic anchorage: a prospective clinical study. (Wiechmann et al , 2007)	Not randomised clinical trial (Cohort)
Mini- and micro-screws for temporary skeletal anchorage in orthodontic therapy. (Berens et al , 2006)	Not randomised clinical trial (Cohort)
Influence of surface characteristics on survival rates of mini-implants. (Cheddad et al. , 2008)	Not a randomised clinical trial. Intervention do not include a type of conventional anchorage.
Loss of anchorage of miniscrews: a 3-dimensional assessment. (ElBeily et al. ,2009)	Not randomised clinical trial (Cohort)
Clinical suitability of titanium microscrews for orthodontic anchorage: preliminary experiences. (Fritz et al. , 2004)	Not randomised clinical trial (Cohort)
Anchorage value of surgical titanium screws in orthodontic tooth movement. (Hedayati et al.,2007)	Not randomised clinical trial (Cohort)
Mini-implant anchorage for maxillary canine retraction: a pilot study. (Herman et al. , 2006)	Not randomised clinical trial (Cohort)
Clinical outcome of miniscrews used as orthodontic anchorage. (Justens & De Bruyn, 2008)	Not a randomised clinical trial. Intervention do not include a type of conventional anchorage.
Comparison and measurement of the amount of anchorage loss of the molars with and without the use of implant anchorage during canine retraction. (Thiruvenkatachari et al. , 2006)	Not randomised clinical trial (Cohort)
Mini-implant anchorage for enmasse retraction of maxillary anterior teeth: a clinical cephalometric study. (Upadhyay et al. , 2008)	Not randomised clinical trial (Cohort)
Mini-implants vs fixed functional appliances for treatment of young adult Class II female patients: a prospective clinical trial. (Upadhyay et al., 2012)	Not randomised clinical trial (Cohort)
Comparison of skeletal and conventional anchorage methods in conjunction with pre-operative decompensation of a skeletal Class III malocclusion. (Wilmes et al., 2009)	Not randomised clinical trial (Cohort)

Article	Reason of exclusion
Clinical use of miniscrew implants as orthodontic anchorage: success rates and postoperative discomfort. (Kuroda et al.,20070	Not randomised clinical trial (retrospective)
Expectations, acceptance and preferences of patients in the treatment with orthodontic mini-implants: part II: implants removal. (Lehnen et al., 2011)	Comparison was performed between two placement types of miniscrews. Intervention do not include a type of conventional anchorage.
Expectations, acceptance, and preferences regarding microimplant treatment in orthodontic patients: A randomized controlled trial. (Baxmann et al., 2010)	Comparison was performed between two placement techniques of miniscrews. Intervention do not include a type of conventional anchorage.
The effect of drill-free and drilling methods on the stability of mini-implants under early orthodontic loading in adolescent patients (Turzkoz et al., 2011)	Comparison was performed between two placement techniques of miniscrews. Intervention do not include a type of conventional anchorage.
A prospective study of the risk factors associated with failure of mini-implants used for orthodontic anchorage.(Cheng et al., 2004)	Not randomised clinical trial (Cohort)
Evaluation of orthodontic mini-implant anchorage in premolar extraction therapy in adolescents.(Grafinkle et al., 2008)	Split mouth design
Immediate vs. conventional loading of palatal implants in humans. (Gollner et al., 2009)	Comparison was between two loading techniques of palatal implants
Contact damage to root surfaces of premolars touching miniscrews during orthodontic treatment. (Kadioglu et al., 2008)	Not a randomised clinical trial. Intervention do not include a type of conventional anchorage.
Displacement pattern of the maxillary arch depending on miniscrews position in sliding mechanics. (Lee et al., 2011)	Not a randomised clinical trial. Intervention do not include a type of conventional anchorage.
Effect of cervical anchorage studied by the implant method. (Melsen & Enemark , 2007)	Interventions do not include miniscrews.
Factors associated with the success rate of orthodontic miniscrews placed in the upper and lower posterior buccal region. (Moon et al, 2008)	Not randomised clinical trial (retrospective)
Application of orthodontic miniimplants in adolescents. (Motoyoshi et al., 2007)	Not randomised clinical trial (Cohort)

4.3.4 Characteristics of the outcomes.

4.3.4.1 Primary outcome.

The primary outcome was the amount of mesial movement of the upper first molar at different time points. It was measured from the beginning of providing anchorage supplement to the end of the anchorage phase in one study (Sandler et al., 2014). One study measured the molar movement from the beginning of the treatment until a class I canine relationship was achieved (Alsibaie & Hajeer 2014). Two studies measured the molar movement before the start of space closure phase to the end of space closure phase (Basha et l., 2010; Upadhyay et al., 2008). The primary outcome was measured from the beginning of the treatment to the end of space closure in one study (Sharma et al., 2012). In one study, the molar movement was not reported (Ma et al., 2008).

4.3.4.2 Secondary outcomes.

Anchorage device failure or success was reported in four studies (Basha et al., 2010; Upadhyay et al., 2008; Sandler et al., 2014; Alsibaie & Hajeer 2014). Two studies reported on the duration of total treatment (Liu et al., 2009 and Sandler et al, 2014) and two studies reported on space closure (Basha et al., 2010; Upadhyay 2008). Only one study reported on the number of visits, harm and patient perception (Sandler et al., 2014).

4.3.5 Risk of bias.

In summary, out of the seven studies included in this review, three studies were assessed as having a high risk of bias overall (Ma et al., 2008; Liu et al., 2009; Basha et al., 2010) and one study was assessed as having an unclear risk of bias (Upadhyay et al., 2008). Three studies were assessed as having a low risk of bias overall (Sandler et al., 2014; Alsibaie & Hajeer 2014; Sharma et al., 2012). Table 10 shows a summary of risk of bias assessment in the included studies.

The studies were assessed for bias in six methodological domains as recommended by the Cochrane Handbook for the Systematic Review of Interventions (Higgins et

al., 2011). The random sequence generation was adequate in all studies except for Basha (2010). Allocation concealment was graded as unclear in two studies (Liu et al., 2009 and Ma et al., 2008) and a high risk of bias in one study (Basha et al., 2010). In four studies (Sharma et al., 2012; Sandler et al., 2014; Ma et al., 2008 and Alsibaie & Hajeer 2014), the outcome assessors were blinded. The remaining three studies were graded as having either a high risk of bias (Liu et al., 2009 and Basha et al., 2010) or an unclear risk of bias (Upadhyay et al., 2008). The risk of bias in the completion of the outcome data reporting domain (Attrition bias) was low on all included studies as the all the patients who were randomised were included in the analysis or they had a small number of dropouts. Selective reporting bias was assessed as being of low risk in three studies (Sharma et al., 2012; Sandler et al., 2014; Ma et al., 2008; Alsibaie & Hajeer 2014). The remaining studies were graded as having a high risk of bias. The other bias domain was judged to be high only in one study (Basha et al., 2010). . The remaining studies were graded as having a high risk of bias. In all the included studies no other potential sources of bias were identified as shown on Table 10.

Table 9 Characteristics of included studies

Author	Settings	Participants (mean age)	Miniscrews arm (total , length , diameter)	Control arm (total)	Arm 3	Primary outcome	Secondary outcome	Mesial movement of the molar in miniscrews mm (SD)	Mesial movement of the molar in control group mm (SD)
Basha et al., 2010	University	14 (16 years, SD 1.41)	7 (14 miniscrews , 8mm, 1.3mm)	TPA (7)	Not Applicable	Mesial molar movement (mm) measured on cephalometrics	Failure rate of miniscrews	0.00 (0.00)	1.73 (0.43)
Liu et al., 2009	University	34 (20.68 years)	17 (34 miniscrews, 8mm, 1.2 mm)	TPA (17)	Not Applicable	Mesial molar movement (mm) measured on cephalometrics	Duration of treatment	- 0.06 (1.4)	1.47 (1.15)
Ma et al., 2008	University	30 (18-22 years)	15 (60 miniscrews ,5 mm length for mandible and 6 mm for maxilla , 1.2 mm)	Headgear (15)	Not Applicable	Cephalometric measurements(molar movement not reported)	Not Recorded	Not reported	Not reported
Sharma et al., 2012	University	30 (17.4 years)	15 (30 miniscrews, 8mm , 1.2 mm)	TPA (15)	Not Applicable	Mesial molar movement (mm) measured on cephalometrics	Failure rate of miniscrews	-0.00(0.02)	2.48 (0.71)

Author	Settings	Participants (mean age)	Miniscrews arm (total , length , diameter)	Control arm (total)	Arm 3	Primary outcome	Secondary outcome	Mesial movement of the molar in miniscrews mm (SD)	Mesial movement of the molar in control group mm (SD)
Upadhyay et al., 2008	University	40 (17.5 years)	20 (80 minicrews , 8mm , 1.3 mm)	Conventional anchorage including headgear, TPA, banding the second molar and application of differential moments (20)	Not Applicable	Mesial molar movement (mm) measured on cephalometrics	Failure rate of miniscrews. Duration of space closure phase.	- 0.78 (1.35)	3.22 (1.06)

Author	Settings	Participants (mean age)	Miniscrews arm (total , length , diameter)	Control arm (total)	Arm 3	Primary outcome	Secondary outcome	Mesial movement of the molar in miniscrews mm (SD)	Mesial movement of the molar in control group mm (SD)
Sandler et al., 2014	University	78(14.22 years)	27 (44 miniscrews , 8mm , 1.6mm)	Headgear (23)	Nance (26)	Mesial molar movement (mm) measured on 3D models.	Duration of anchorage reinforcement and total treatment. Number of treatment and emergency visits. Patient perception	Right 0.8 (1.6) Left 0.99 (1.15)	- Headgear Right 1.36 (1.83) Left 1.99 (2.09) - Nance Right 1.84 (1.32) Left 2.09 (1.32)
Alsibaie & Hajeer, 2014	University	56 (22.4 years)	28 (56 miniscrews , 7 mm, 1.6 mm)	TPA (28)	Not Applicable	Mesial molar movement (mm) and upper anterior teeth measured on cephalometrics	Not recorded	- 0.89 (0.59)	1.50 (1.25)

Table 10 Risk of Bias summary for included studies

Author	Year	Study type	Random sequence generation	Allocation concealment	Blinding of assessors	Incomplete outcome data	Selective reporting	Other bias	Results of Bias
Sharma et al	2012	RCT	Yes	Yes	Yes	Yes	Yes	Yes	Low risk
Liu et al	2009	RCT	Yes	Unclear	No	Yes	No	Yes	High Risk
Sandler et al	2014	RCT	Yes	Yes	Yes	Yes	Yes	No	Low Risk
Upadhyay et al	2008	RCT	Yes	Yes	Unclear	No	No	Yes	Unclear
Alsibaie & Hajeer	2014	RCT	Yes	Yes	Yes	Yes	Yes	Yes	Low risk
Ma et al	2008	RCT	Yes	Unclear	Yes	Yes	No	Yes	High risk
Basha et al	2010	RCT	Unclear	No	No	Yes	No	No	High risk

4.3.6 Meta-analysis.

4.3.6.1 Mesial Movement of the upper first molars.

Six studies with appropriate reporting of the primary outcome were included in the meta-analysis (Sharma et al., 2012; Liu et al., 2009; Upadhyay et al., 2008; Basha et al., 2010; Sandler et al., 2014; Alsibaie & Hajeer 2014) as shown in Figure 24. One study was not included in the meta-analysis because the reporting of the primary outcome was incomplete (Ma et al., 2008).

Data on 282 participants were included in a random effects meta-analysis to assess the anchorage effectiveness of miniscrews when compared with conventional methods. The conventional methods included headgear, TPA, banding of second molar and differential methods. The overall mean difference between the two groups was 2.206mm in favour of miniscrews (MD= -2.20; 95% -1.21 to -3.19). These findings should be interpreted with caution as the amount of heterogeneity across the studies was high (Q = 85.06, DF= 6, P= 0.000, I^2= 92.9%).

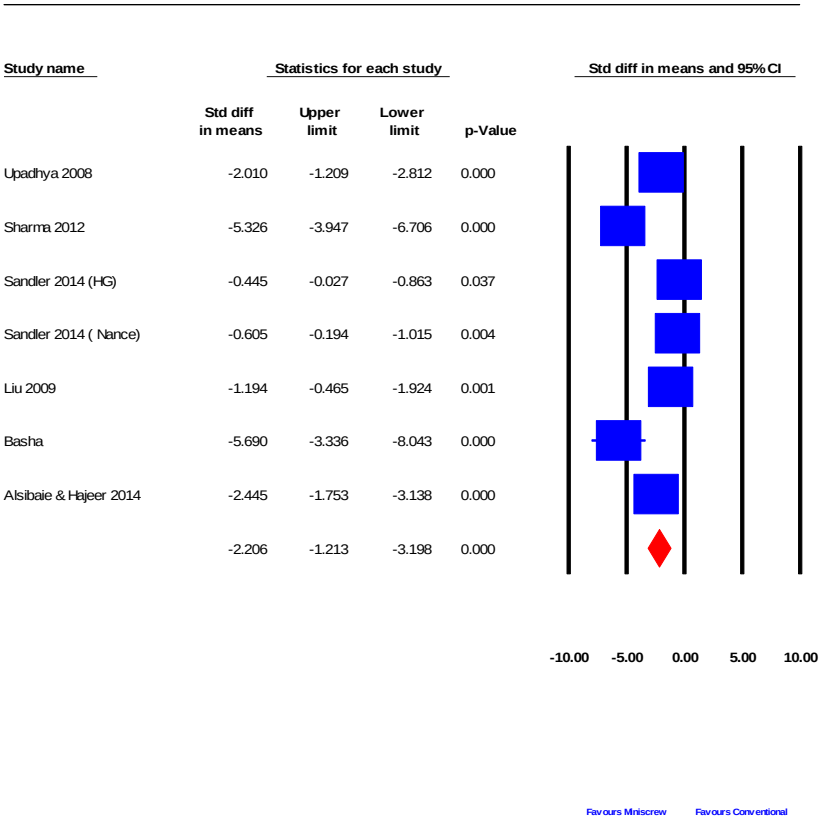


Figure 24 Forest plot of anchorage loss (all studies)

When I analysed the studies with a low risk of bias overall only (Sharma et al. 2012; Sandler et al., 2014; Alsibaie & Hajeer 2014), the over mean difference was 2.036 of molar movement in favour of miniscrews (MD= -2.036; 95% -0.68 to – 3.39, Q = 64.818, DF= 3, P= 0.000, I^2= 95%) as shown in Figure 25. Because of the high heterogeneity across the studies, these findings should be interpreted with caution.

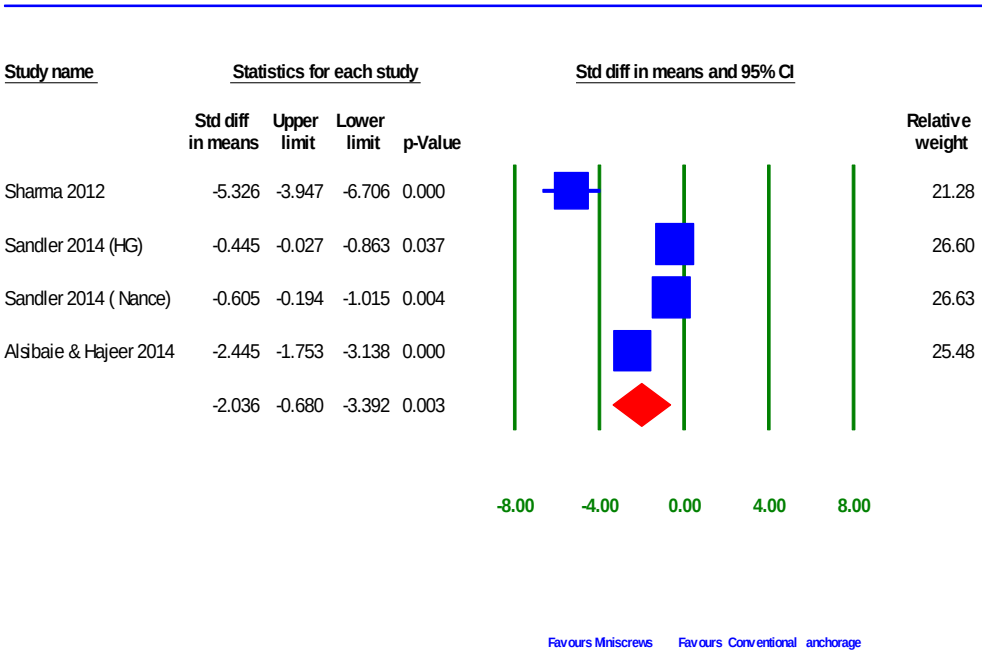


Figure 25 Forest plot of anchorage loss (studies with low risk of bias only)

4.3.6.2 Duration of Treatment.

The duration of the treatment was reported in two studies (Liu et al., 2009 and Sandler et al., 2014). Data on 105 participants were pooled in a fixed effect model meta-analysis as shown in Figure 26. The difference in the means of the treatment duration was 0.14 months in favour of miniscrews (95% -0.489 to 0.208, P= 0.430, Q = 0.093, DF= 2, P= 0.995, I^2= 0%).

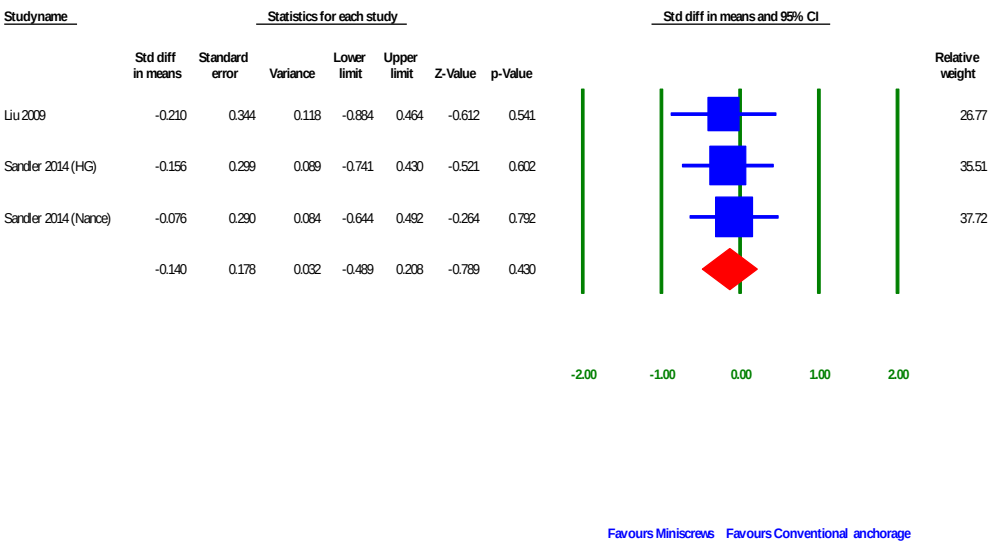


Figure 26 Forest plot of treatment duration

4.3.6.3 Number of visits.

Only one study (Sandler et al., 2014) reported on the number of visits required to complete the treatment. The mean number of visits required to complete orthodontic treatment was 18.38 (SD 5.95) for miniscrews group, 19.24(SD 6.42) for headgear group and 21.77(SD 4.41) Nance group.

4.3.6.4 Patient perception

Only Sandler et al. (2014) reported on pain. The data he derived from the 6-point Likert scale were provided by patients about their experience of the placement and removal of miniscrews and Nance (Table 11).

Table 11 The 6-point Likert scale, 1 representing uncomfortable and 6 representing comfortable, measures the patients' perception of discomfort of the placement and removal of miniscrews or Nance.

Anchorage methods	Placement comfort	Comfort during 1st 3days	No. of discomfort days	Removal comfort	Discomfort After 3 days	Discomfort duration in days
Miniscrews	4.41(1.1)	3.73(1.55)	2.82(2.11)	4.25(1.41)	4.81(1.54)	1.00(1.4)
Nance	4.62(1.3)	3.46(1.48)	2.65(2.04)	4.31(1.44)	4.92(1.06)	1.12(1.73)

Sandler et al. (2014) reported on patients' experience of headgear as well (Table12).

Table 12 The 6-point Likert scale, 1 representing uncomfortable and 6 representing comfortable, measures the patients' experience with headgear wear discomfort

Headgear	Hours requested	Actually worn HG	Months	Comfort	Convenience	Social interference	Did it bother you?
Mean	13.87	10.87	8.98	2.87	2.91	3.78	2.76
SD	3.31	4.01	4.73	1.39	1.41	1.51	1.55

Sandler et al. found the participants' free text comments almost always positive about miniscrews, unlike Nance and headgear. 20 out of 22 participants would recommend miniscrews to others; while only 20 of 26 in the Nance group, and 13 of

23 in the headgear group would recommend to their peers the anchorage method to which they were allocated.

4.4 Discussion

The findings from this review suggest that miniscrews are more effective in providing anchorage than conventional methods of anchorage. A meta-analysis of the pooled data estimated the difference between miniscrews and headgear and transpalatal arch to be 2.206 mm (SD 0.99) in favour of miniscrews. The difference in the means between the two groups was 2.03mm (SD 1.35) when pooled data were extracted from studies with an overall low risk of bias. It is interesting to note that all of the studies with a low risk of bias were recent studies. However, this result should be interpreted with caution due to the high level of heterogeneity across the studies.

Jambi et al. (2014) in a Cochrane review estimated the difference between surgical anchorage and conventional anchorage to be 1.68 mm (95% CI, 2.27-1.09) in favour of surgical anchorage. Although they included in the surgical anchorage group different types of implants unlike us, their estimate did not differ significantly from our estimate. However, when they pooled data for miniscrews which were extracted from only four studies, the mean difference was 2.17 mm (95% CI, 2.58 to -1.77) in favour of miniscrews which is similar to our estimate.

Papadopoulos and Papageorgiou (2013) performed a systematic review investigating the effectiveness of miniscrews in providing anchorage reinforcement during orthodontic treatment. The included 8 prospective studies (five controlled clinical trials and three randomised clinical trials) and found miniscrews were more effective than conventional anchorage methods. They estimated the mean difference to be 2.4 mm less in favour of miniscrews (95% CI, 1.8-2.9). That was in accordance with our findings.

Lie et al. (2011) performed a systematic review to investigate the anchorage effectiveness of implants (not only miniscrews) and headgear. They included randomised clinical trials, prospective cohort studies and retrospective controlled studies. The result of their search included only eight studies (four randomised

clinical trials, one prospective cohort study and three retrospective studies). They found that the mean difference was 1.34 mm (95% CI, 2.02-0.67) in favour of implants. This estimate was reported when they pooled the data of two studies only out of the eight studies (Feldman et al., 2007; Sandler et al., 2008). It is not possible to compare their findings with ours due to the differences in the focus between the two reviews.

Other outcomes such as the treatment duration and patients' perceptions in this review were reported in a small number of the studies. The findings of this review revealed that treatment duration was shorter with miniscrews. The data was extracted from two studies. Jambi et al. (2014) found similar results. However, their estimate was different as they had indicated that treatment with surgical anchorage was shorter by 0.25 months. We have found that treatment with miniscrews was shorter by 0.14 months. It is worth noticing that they pooled the data from three studies where two of them used palatal implants (Borsos et al., 2012; Sandler et al., 2008) and only one study used miniscrews (Liu et al., 2009). Whereas we extracted the data about treatment duration from two studies (Liu et al., 2009; Sandler et al., 2014). The different estimation of how much shorter the treatment was can be explained by the different inclusion criteria between the two reviews.

Number of visits was reported in single studies in both reviews. In Jambi et al. (2014) review, only Sandler et al. (2008) reported the number of visits and found that treatment takes 7 visits more to be completed by surgical anchorage. Sandler and his colleagues pointed out that they did not include the visits required for surgical placement of midpalatal implants. In this review, the study included was Sandler et al. (2014) who found that treatment with miniscrews required less visits than the one with headgear and Nance.

Patients' perception was reported only in one study in this review (Sandler et al., 2014) which found that patients had positive perception about miniscrews unlike headgear and Nance. In Jambi et al (2014) review two studies (Feldmann et al., 2007; Sandler et al., 2008) reported on patient perception. Both studies did not use miniscrews which makes the comparability between the two reviews not possible.

The finding of this review should be interpreted with caution due to the substantial heterogeneity across the studies. This high level of heterogeneity could be a result of different interventions used in the included studies, variation in the sample size and different methods of anchorage assessment. Statistical analysis of the publication bias was not performed in this review as only a few studies were included (Lau et al., 2006). The limited data on the secondary outcomes do not allow a definite judgment on the miniscrews or conventional anchorage regarding the total treatment duration or patients' perceptions.

4.5 Conclusion

In this systematic review, the effects of miniscrews were assessed in comparison to conventional anchorage methods during orthodontic treatment. The mesial movement of the upper first molar measured in millimetres was evaluated. Seven randomised clinical trials conducted in university settings were included in the review. The total risk of bias of the trials was divided into low or high risk of bias equally between the six trials. Only one trial was assessed as having an unclear risk of bias. The pooled results indicated that the difference in mean was in favour of miniscrew.

Chapter 5.

Reporting of clinical trials in the orthodontic literature from 2008-2012: Observational study of published reports in four major journals

5.1 Introduction

Well conducted and reported randomised clinical trials (RCTs) are considered the foundation of evidence based dentistry today. Poorly conducted RCTs can either overestimate or underestimate the effect of the tested treatment. To be able to assess the quality of a RCT accurately, readers of a published report need complete, clear, and transparent information on its methodology, analysis, and findings (Schulz et al., 2010). Unfortunately many trial reports fail to provide clear and complete descriptions making it difficult to assess the study quality.

The lack of adequate reporting fuelled the development of the original CONSORT (Consolidated Standards of Reporting Trials) statement in 1996 (Begg et al., 1996), its revision 5 years later (Moher et al., 2001) and further updates in 2010 (Schulz et al., 2010). Statisticians, editors and researchers met together to decide which elements of RCTs should be reported when the findings are disseminated. The statements recommendations were meant to enhance the complete and transparent reporting of RCTs and to enable their critical analysis. CONSORT group members have presented a 37-point checklist of information to be considered when reporting an RCT.

The CONSORT statement has been endorsed by 585 different journals to date, representing over 50% of the core medical journals listed in the Abridged Index Medicus on PubMed (CONSORT statement, 2011). The CONSORT statement stimulated the establishment of the EQUATOR (Enhancing the Quality and Transparency Of health Research) network. The EQUATOR initiative aimed to enhance the reporting of health research (Altman et al., 2008). Beside the CONSORT statement for RCTs, this international initiative adapted guidelines for observational studies, systematic reviews, case reports, qualitative research, diagnostic/prognostic studies, quality improvement studies, economic evaluation, animal pre-clinical studies and study protocols. Also, the initiative offers training for researchers to improve their understanding and use of the guidelines

Studies in different medical disciplines have looked at research quality and reporting quality in medical research. Several investigations in the medical literature have found that the quality of reporting is inadequate. Mills et al. (2005) evaluated the quality of reporting RCTs in five leading general medical journals and found that

reporting was inadequate. Two systematic reviews (Plint et al., 2006, Falagas et al., 2009) of studies evaluating the quality of RCT reporting in different medical specialities and a Cochrane review (Turner et al., 2012) have been published. Both systematic reviews found that although endorsement of CONSORT statement by journals improved RCT reporting, authors still report their trials inadequately. In dentistry, Pandis et al. assessed the quality of RCT reporting in dental speciality journals with the highest impact factor and found that quality of reporting is suboptimal with a 62% mean score for completeness of reporting with regard to the CONSORT statement check list (Pandis et al., 2010).

Harrison assessed 155 trials published in three orthodontic journals between 1989 and 1998, using the Jadad scale for the assessment of the quality of RCTs. She found that 137 trials had a high risk of bias, 17 trials had moderate risk of bias, and only one trial had low risk of bias. She also concluded that in orthodontics, reporting of RCTs before the CONSORT statement in 1996 was often insufficient to allow readers to assess the quality of trials (Harrison, 2003).

In a further study, Flint and Harrison assessed reporting of RCTs in four orthodontic journals at three time points (1995/6 pre-CONSORT, 2000/1 post-CONSORT and 2005/6 post revised CONSORT) on the basis of the checklist developed from the CONSORT statement. They found that the quality of reporting RCTs had improved over time, but reporting of randomisation, allocation concealment and blinding remained inadequate (Flint and Harrison, 2010).

The aim of this study was to provide an update as to whether authors in the orthodontic field of research currently report RCTs adequately as defined by the CONSORT statement checklist. In this chapter, I will present the material of the study which was the topic of a publication co-authored with Bearn in the Journal of Orthodontics (appendix 1).

5.2 Materials & Methods

5.2.1 Identification of clinical trials

Clinical trial reports were retrieved from the major journals in orthodontics in which 71.43% of clinical trials were published (Shimada et al., 2010). The American Journal of Orthodontics and Dentofacial Orthopedics (AJO-DO) is the official publication of the American Association of Orthodontists, its constituent societies, the American Board of Orthodontics and the College of Diplomats of the American Board of Orthodontics. It has been published for more than a century now. This peer-reviewed journal publishes reports related to different orthodontic treatment phases. It is the highest orthodontic ranked journal by the number of citations in the Journal Citation Reports®, published by Thomson Reuters with impact factor of 1.690 in 2015. The journal is published on a monthly basis.

The Journal of Orthodontics (JO) is the official publication of the British Orthodontic Society. It publishes clinically oriented or clinically relevant papers in relation to orthodontic treatment. This peer-reviewed journal publishes an issue every three months. The impact factor of the journal was not reported in Journal Citation Reports®, published by Thomson Reuters.

The third journal is the Angle Orthodontist (AO), which is the official publication of Edward Angle Society of Orthodontists. This non-commercial, non-profit journal publishes an issue every two months. It has impact factor of 1.579 according to Journal Citation Reports®, published by Thomson Reuters.

The last journal investigated is the European Journal of Orthodontics (EJO). It is the official publication of the European Orthodontic Society but it welcomes publications related to orthodontics from all around the world. According to Journal Citation Reports®, the journal has an impact factor of 1.440. Like the AJO-DO, EJO publishes 12 issues per year.

The title and abstract of all published articles between January 2008 and June 2012 in the four journals were reviewed by one of the authors (FA). Identification of the clinical trials was through searching the title and the abstract for the keywords ‘Trial‘, ‘Randomised’ or ‘Assigned‘ and then retrieving full text for all articles that include

one or more of these terms. Full-text articles that reported randomised or controlled clinical trials were retrieved for further assessment.

5.2.2 Assessment of the trial reporting

The CONSORT 37 item-check list was used to score the reports (Figure 27). Each item was scored either as 'Yes' if present, 'No' if absent, or 'Not applicable' (NA). An item was scored as not applicable if the design of the study made it impossible to include. The total score for each trial was calculated and converted to a percentage using the equation: Total score = (total number of 'Yes'/ [37 - total number of 'NA 'items]) x 100.

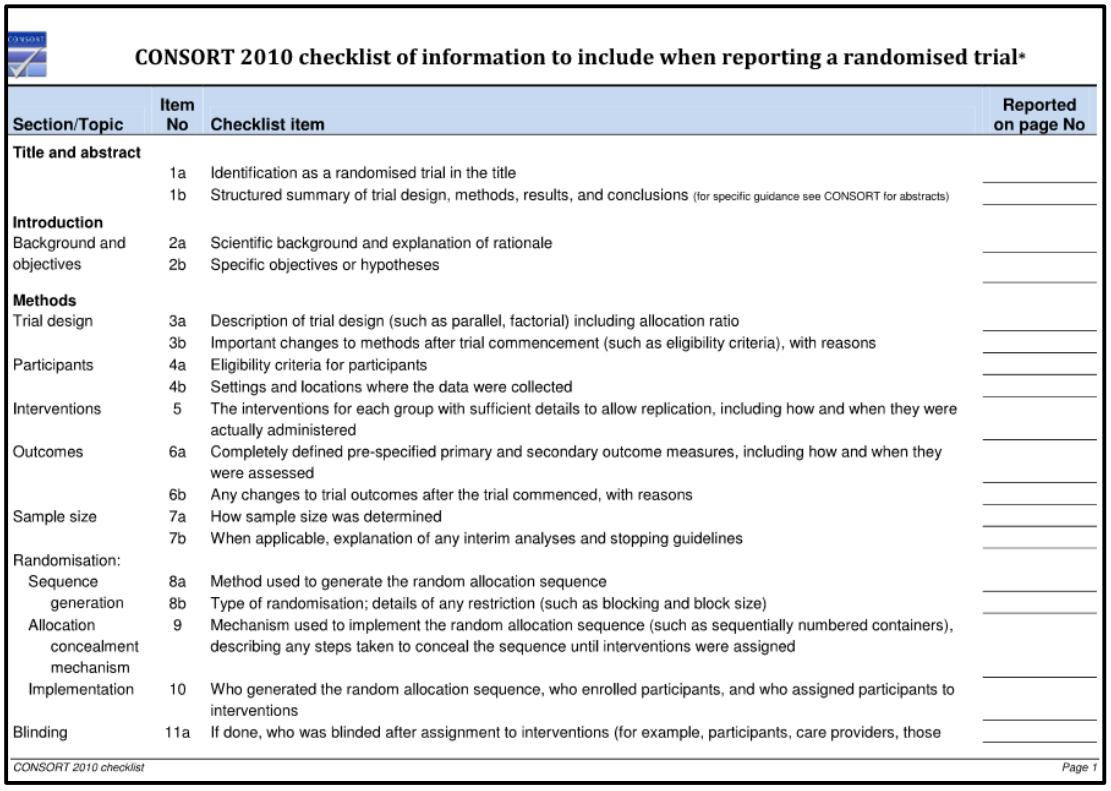
5.2.3 Additional data collected

Information related to the following characteristics was also recorded for each article:

- Number of authors
- Continent and country of first author
- Clinical setting of the trial

5.2.4 Reliability

A 10% random sample of the papers was scored by a second examiner (DB) to assess inter-examiner reliability of the CONSORT score. Another 10% random sample of the papers was scored a second time by the first examiner (FA) three months after initial data collection was completed to test intra-examiner reliability.



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist — Page 1

CONSORT 2010 checklist — Page 2

Figure 27 CONSORT 2010 checklist

5.3 Results

Out of 3335 articles reviewed in the four journals from January 2008 – June 2012, one hundred and fifty one (4.6%) clinical trial reports were identified (Table 13). The AJODO published most reports (78) while the JO published the fewest (9) as presented in Figure 28. Mean CONSORT score for all the trial reports was 51.7%. The scores ranged from 73.6 % for the JO to 44.5% for the AO.

Table 13 Number of publications, mean CONSORT Score, and randomisation reporting by publication

	All journals	**AJO-DO**	**JO**	**AO**	**EJO**
Number (%) of published RCTs	151	78 (51.7%)	9 (6.0%)	43 (28.5%)	21 (13.9%)
Mean (SD) CONSORT Score	51.7 (13.1)	53.9 (11.2)	73.6 (7.1)	44.5 (11.9)	48.9 (11.1)
Randomisation reporting adequate	7.90%	6.40%	67%	23%	0
Randomisation reporting inadequate	35.8	47.40%	22%	74%	76%
Randomisation not reported	56.30%	46.20%	11%	3%	24%

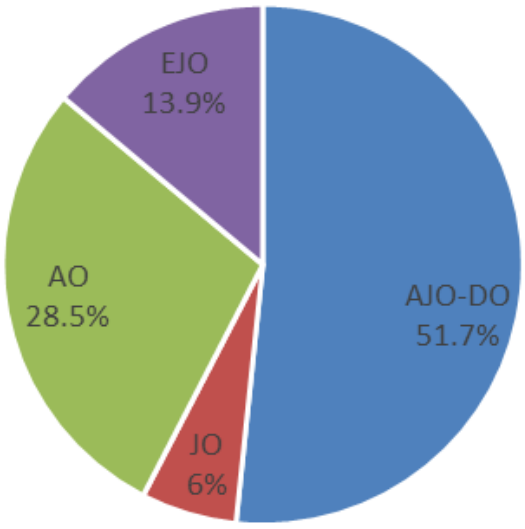


Figure 28 Distribution of reports accoding to journals

Mean CONSORT score by year of publication increased from 47.8% in 2008 to 56.3% in 2012 (Table 14). Twelve (7.9%) out of the 151 papers satisfactorily reported all the five items related to the method of randomisation. Of the remaining 139 articles, reporting of randomisation was inadequate in fifty four reports (35.8%) and eighty five reports (56.3%) did not give details of randomisation methods (Figure 29).

Table 14 Number of publication and mean consolidated standards of reporting trials (CONSORT) score

Year of Publication	Number of publications	Mean CONSORT Score	Std. Deviation
2008	45	47.8	11.2
2009	26	51.5	11.1
2010	24	51.8	14.2
2011	37	54.3	13.6
2012	19	56.3	15.2
Total	151	51.7	13

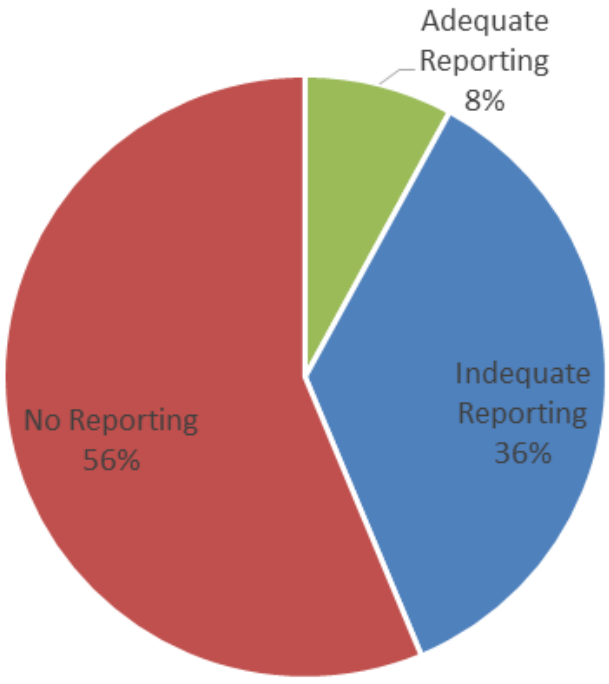


Figure 29 Reporting five items related to the method of randomisation in CONSORT

In 93% of reports the first author worked in an academic institution and 50% of trials were reported by four or five authors (Figure 30). Eighty four percent of the trials were set in university clinics, 9.3 % were in private practice and 6.6 % were in hospital or public clinics. (Figure 32)

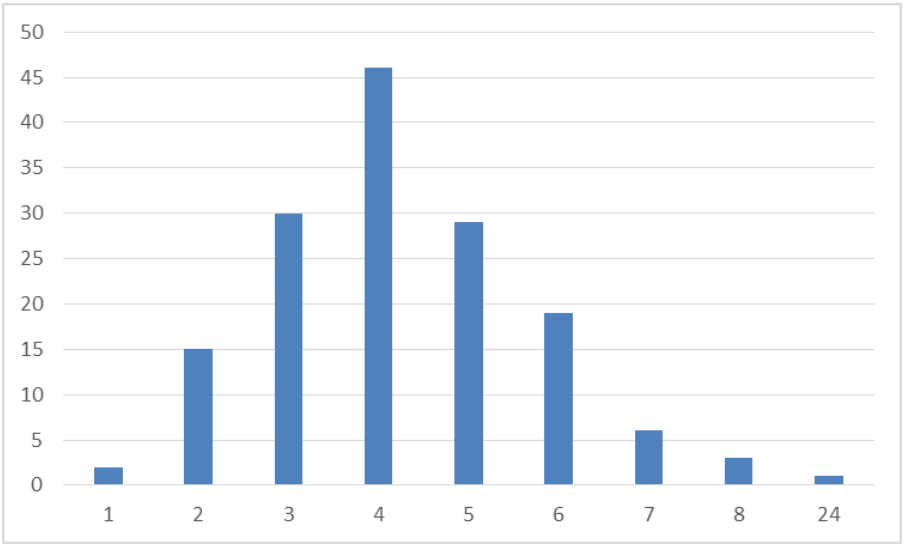


Figure 30 Number of authors

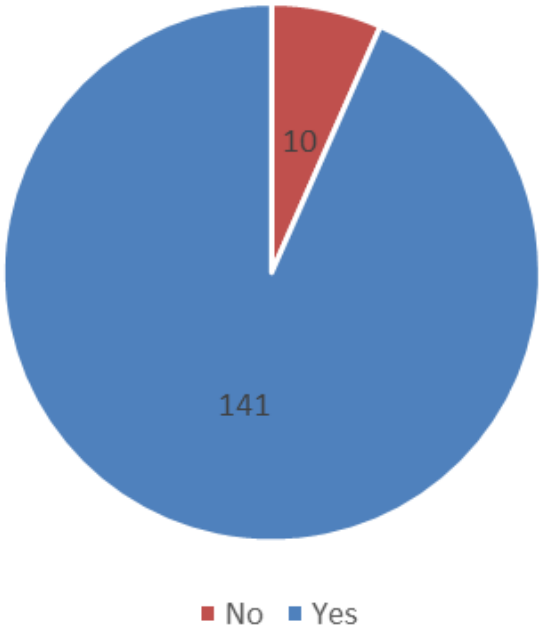


Figure 31 Setting was academic institution or not

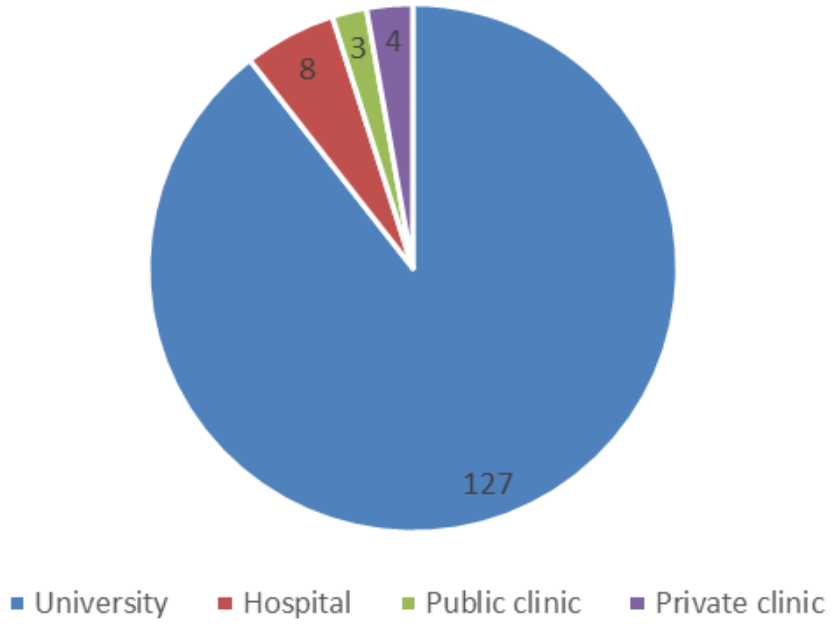


Figure 32 Settings of the trial

More than half of publications were from Europe (54.3%) (Figure 33) and Turkey contributed most (18.5%) followed by the USA (15.9%) and the UK (11.9%) as shown in Figure 34.

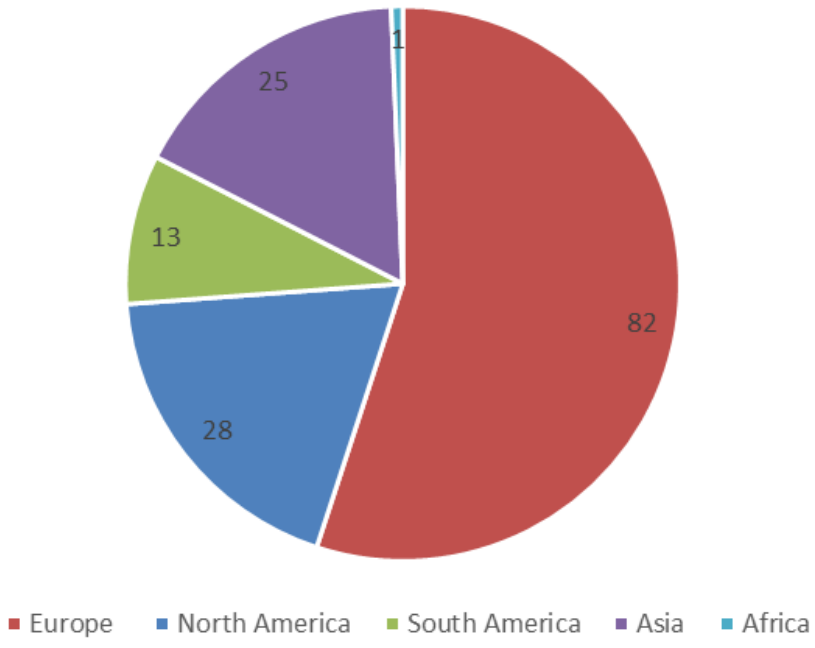


Figure 33 Distribution of first authors by continent

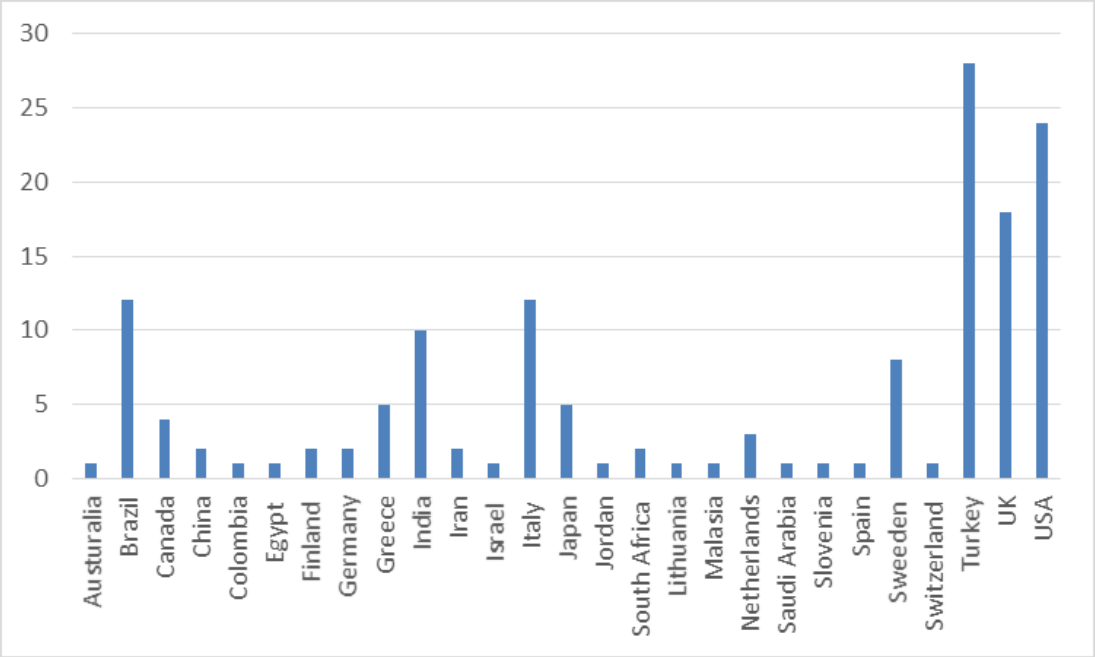


Figure 34 Distribution of first authors by country

Reliability

Bland and Altman plots, where the difference between the two methods was plotted against the mean (Figure 35 & 36) showed no systematic error in the CONSORT checklist scoring and the random error was deemed to be within acceptable limits for both inter-examiner and intra-examiner reliability as the difference in scoring a trial was small.

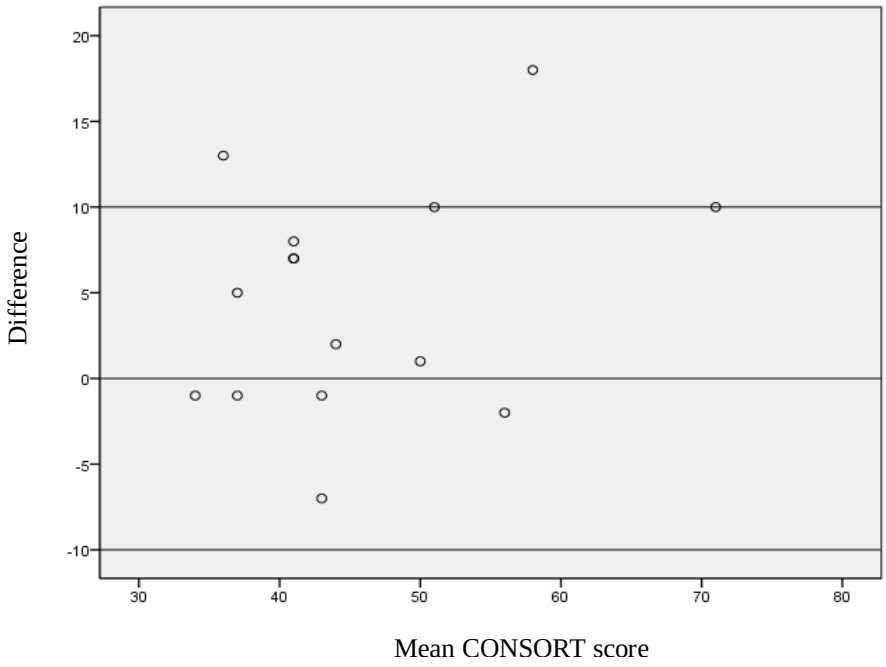


Figure 35 Bland -Altman plot for intra-examiner reliability test

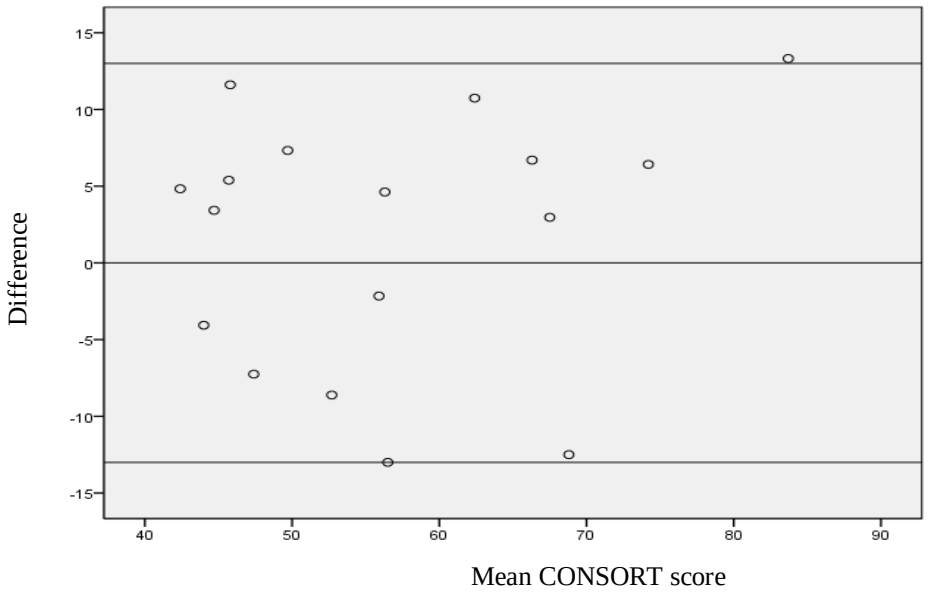


Figure 36 Bland-Altman plot for inter-examiner reliability test

5.4 Discussion

This retrospective study has looked into the quality of reporting of orthodontic RCTs which contribute to systematic reviews and drive evidence based dentistry. The number of RCTs in the orthodontic literature is small, and so it is important they are planned, conducted and reported to a high standard. Indeed, they account for only 5.26% of articles published in the AJO-DO (Pandis et al., 2011) which is consistent with the findings of this study. In addition, some trials are the subject of multiple reports, which means this may be an overestimation of the actual number of RCTs carried out in orthodontics.

The findings of this study highlight that a gap still exists between current RCT reporting in orthodontics and the high standard of reporting according to the CONSORT statement. The JO was the first of the included journals to endorse the CONSORT statement and scored highest (73%), whilst the lowest compliance score was achieved by the AO (44%), which did not endorse the CONSORT statement at the time of collecting the data for this study. Adopting the CONSORT statement by three of the four journals appears to have contributed to improving the quality of reporting of clinical trials through time from 48% in 2008 to 56% in 2012, showing a continued trend from the finding of Flint and Harrison (2010) that in 2006 the journals achieved a mean score of 42.5%. This improvement appears likely to be as a result of raised awareness of researchers, journals editors and funding bodies of the importance of complete reporting informed by the CONSORT statement. In addition, legislating authorities including the EU commission now require transparent reporting of clinical trials, a decision that may have also raised awareness of the important of correct reporting (Commission of the European Communities, 2006).

The essential elements that characterize a RCT are randomization, blinding and concealment. Double-blinding is often difficult to achieve in RCTs in orthodontics but blinding of assessors is still achievable. An investigation of whether reports entitled as RCT were in fact RCTs found that 46.4% of them have an unclear description of randomization procedures (Koletsi et al., 2012b). This compares with our study where we found that 35.8% of the reports had inadequate reporting of randomization procedures and 54.6% of the reports had no details of the randomization procedure. Absent or inadequate reporting could result from lack of understanding of researchers about the importance of the detail of randomization procedures to assess risk of bias, deliberate ambiguity or limited space in some journals.

An interesting finding of this study was that the vast majority (93%) of clinical trials were undertaken in an academic environment, despite most orthodontic treatment being provided outside this environment. Trials conducted in private clinics represented less than 10% of clinical trials in orthodontics. Generalising the findings of RCTs carried out in an academic clinic setting to a private clinic setting should be done with caution as case selection and clinical experience may significantly influence the outcome.

During the period of this study, the majority of trial reports were from Europe, followed by the USA. Interestingly a large number of clinical trials reports came from Turkey, which may be a result of the improvement in the Turkish economy in the last decade. In a Thomson Reuter global research report, the number of published research articles from Turkey increased from 5000 reports in 2000 to 22,000 reports in 2009 (Adam et al., 2011).

One limitation of this study relates to the sample size, which prevented statistical comparison between journals. Another limitation of this study may arise from the fact that scoring certain items of the CONSORT checklist has a degree of subjectivity. Inter and intra examiner reliability tests indicate the effects of this subjectivity were limited.

Conducting a RCT requires significant resource and everyday clinical practice depends on their outcomes. Therefore reporting the clinical trial to a high standard to allow readers to make a valid judgement on the risk of bias and quality is as important as designing and conducting them correctly. We support the conclusion of other researchers (Turpin, 2005; Flint and Harrison,2010; Koletsi et al., 2012a; Seehra et al., 2013) that it is the duty of researchers, journals editors and funding bodies to ensure the continued improvement in the standard of reporting of RCTs.

5.5 Conclusion

- Clinical trial reports represented less than 5% of articles in the four main orthodontic journals between 2008 and 2012.
- CONSORT mean score ranged from 44.5% to 73.6% between journals.
- CONSORT mean score increased through the period of investigation.

Chapter 6.

British Orthodontic Society national audit of temporary anchorage devices (TADs): report of the first thousand TADs placed.

6.1 Introduction

Clinical audit is a process where the current performance is evaluated against agreed standards to improve the quality of provided care. The benefits of audit and feedback are most likely to happen as health professionals would modify their practice if provided with feedback about their performance compared to agreed guidelines.

The National Institute for Health and Clinical Excellence (NIHCE), a component of the UK National Health Service concerned with raising the standards of health and social services by providing recommendations, guidance and standards to care providers, reported on the use of TADs and provided recommendation for clinicians related to clinical audit (NICE, 2007). This project complies with the NIHCE recommendations by reporting the findings of the British Orthodontic Society (BOS) UK national clinical audit on TADs to allow individuals to compare their own experience to the UK national average (Sandler, 2009). The British Orthodontic Society is committed to clinical audit to improve provided healthcare and is involved in number of national and regional audit projects including this audit. In this chapter I will present the findings of this clinical audit which was the topic of a publication co-authored with Bearn in the Journal of Orthodontics in 2015 (appendix 1).

6.2 Materials and methods

This audit was co-ordinated by the BOS and data collected from 71 sites around the UK (Figure 37). Members of the BOS were invited to participate if they were placing TADs by registering on-line (Figure 38) or by completing a registration form (Figure 39).

Figure 37 Audit sites distribution

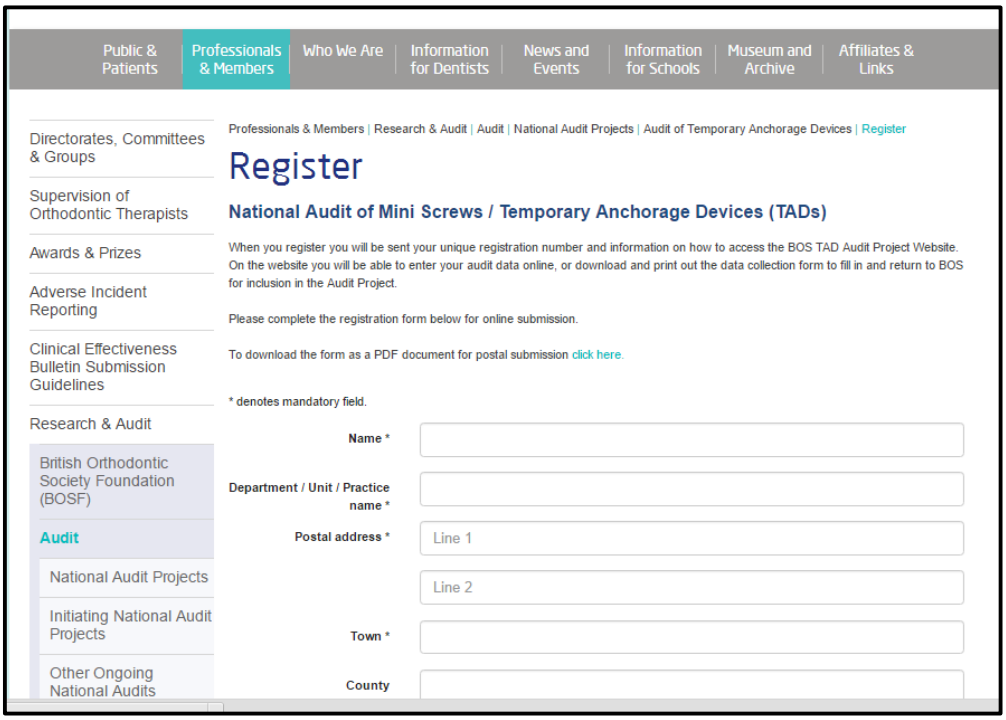


Figure 38 Online registration

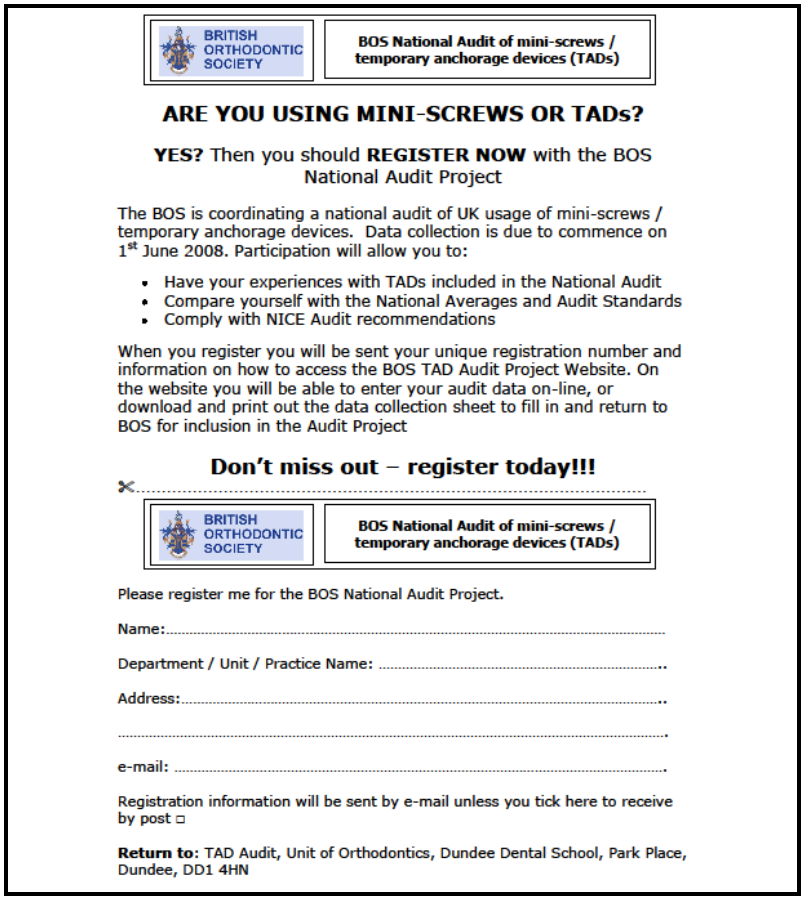


Figure 39 Hard copy registration form

6.2.1 Audit Standards

Proposed standards of this audit were set following the NICE report and with the Standards and Development Committee of BOS. The audit project was submitted to the Committee in November 2007 in line with the published process. Standards were not set in all the areas in the NICE report thus the Committee agreed on the proposed standards to be used in the audit. Derived standards are presented in Table 15. Registration for the audit commenced in May 2008.

Table 15 Audit standards

	Data	Standard
BASELINE DATA		
Was written information on procedure given to patient?	Y/N	**100%**
Documented discussion re procedure & risks	Y/N	**100%**
Signed consent form present	Y/N	**100%**
Type of screw	Name	
Length and width of screw	mm	
Point of insertion	Maxilla/mandible Buccal/lingual Adjacent teeth	
Was a flap raised / incision made?	Y/N	
Was drilling with a pilot drill performed?	Y/N	
Was drilling with a burr performed?	Y/N	
Was a stent used to aid placement?	Y/N	
Was the TAD loaded immediately?	Y/N	
FOLLOW-UP DATA		
Screw lost or removed before completion of anchorage period?	Y/N	**<20%**
Screw replaced following loss or removal?	Y/N	
Anchorage required provided by screw without adverse effects?	Y/N	**70%**
ADVERSE EFFECTS		
Infection / inflammation around screw resulting in loss/removal?	Y/N	**<20%**
Damage to neighbouring teeth	Y/N	**0%**

6.2.2Data collection

Data collection was done prospectively using two forms distributed to participating clinicians using a system of both on-line data entry (Figure 40) and hard copy forms (Figure 41). The first form collected baseline data at time of TAD insertion while the second form collected follow-up data at end of TAD use. Each TAD was

identified using an operator registration number, and unique patient ID. In case of uncertainty or missing data, the participating orthodontist was contacted to provide additional information.

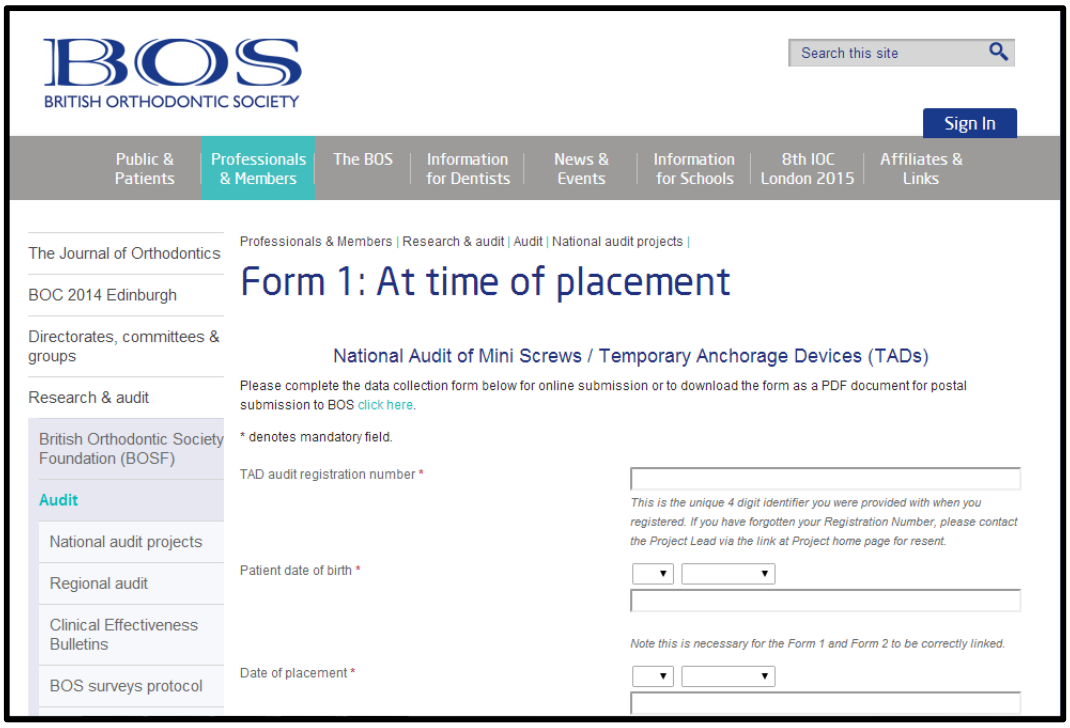
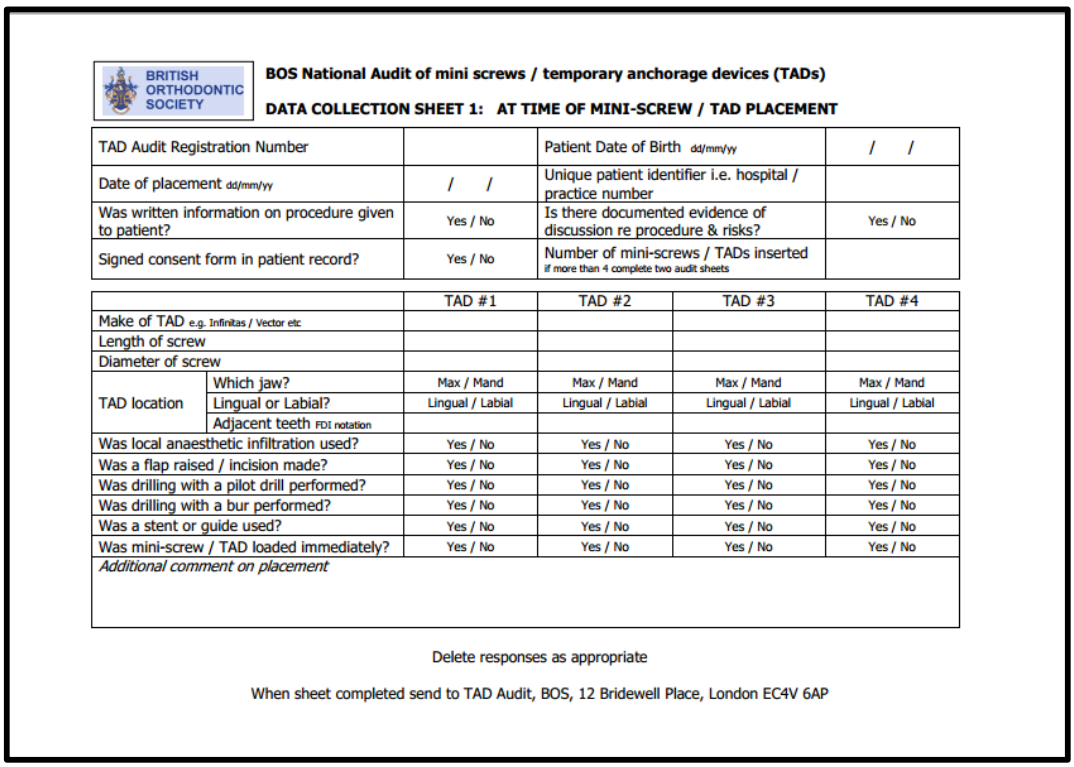


Figure 40 Online data entry



BRITISH ORTHODONTIC SOCIETY

BOS National Audit of mini screws / temporary anchorage devices (TADs)

DATA COLLECTION SHEET 1: AT TIME OF MINI-SCREW / TAD PLACEMENT

TAD Audit Registration Number		Patient Date of Birth dd/mm/yy	/ /
Date of placement dd/mm/yy	/ /	Unique patient identifier i.e. hospital / practice number	
Was written information on procedure given to patient?	Yes / No	Is there documented evidence of discussion re procedure & risks?	Yes / No
Signed consent form in patient record?	Yes / No	Number of mini-screws / TADs inserted if more than 4 complete two audit sheets	

		TAD #1	TAD #2	TAD #3	TAD #4
Make of TAD e.g. Infinitas / Vector etc					
Length of screw					
Diameter of screw					
TAD location	Which jaw?	Max / Mand	Max / Mand	Max / Mand	Max / Mand
	Lingual or Labial?	Lingual / Labial	Lingual / Labial	Lingual / Labial	Lingual / Labial
	Adjacent teeth FDI notation				
Was local anaesthetic infiltration used?		Yes / No	Yes / No	Yes / No	Yes / No
Was a flap raised / incision made?		Yes / No	Yes / No	Yes / No	Yes / No
Was drilling with a pilot drill performed?		Yes / No	Yes / No	Yes / No	Yes / No
Was drilling with a bur performed?		Yes / No	Yes / No	Yes / No	Yes / No
Was a stent or guide used?		Yes / No	Yes / No	Yes / No	Yes / No
Was mini-screw / TAD loaded immediately?		Yes / No	Yes / No	Yes / No	Yes / No
Additional comment on placement					

Delete responses as appropriate

When sheet completed send to TAD Audit, BOS, 12 Bridewell Place, London EC4V 6AP

Figure 41 Hard copy form

6.2.3 Data Analysis

The data were inputted in Excel spreadsheet (Microsoft Excel 2013, Microsoft Corp., Redmond, WA) and then transferred to SPSS for analysis (version 15.0; SPSS, Chicago, IL). Chi-squared test was used to investigate categorical variables on failure rate.

6.3 Results

6.3.1 Descriptive Analysis

Data on the initial 1072 TADs with completed insertion (Form 1) and outcome (Form 2) information collected from 1st May 2008 to 1st November 2013 were included. These TADs were inserted in the period between 1 January 2008 and 1 November 2013 and were placed in 643 patients treated in 71 sites where the orthodontic practitioners were registered for the audit. Sixty two per cent of registrations in the audit were based in the hospital sector, with the remaining 38% in a practice setting. The patient age average was 22 years and ranged from 10-68 years. More than half of them were between 15-20 years as presented in Figure 42. Figures 43-45 report on the distribution of miniscrews according system, length and diameter.

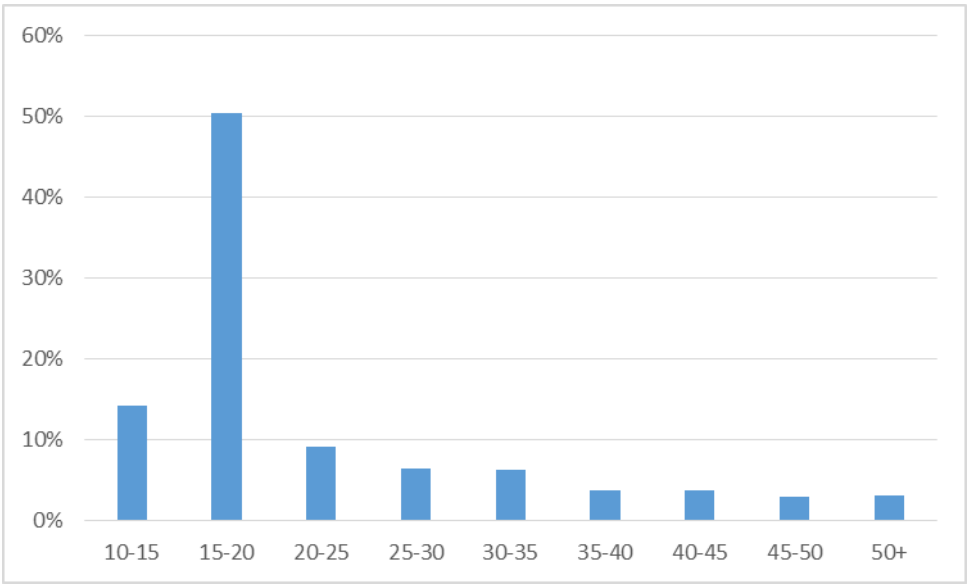


Figure 42 patients age distribution

Infection or inflammation around the TAD resulting in loss or removal was reported in 5.6 % of TADs, which met audit standards (< 20%). The rest of the audit standards were not met as shown in Table 16.

A total of 813 (75.8%) TADs were removed electively by the operator whilst 259 (24.2%) failed. Of the 259 TADs that failed, 93.1% were related to excess mobility, 20.1% to inflammation and 2.3% to infection. Root damage was reported as an adverse effect in seven cases (0.7%). Of the 259 TADs that failed, 37.4% were replaced with a further TAD. In the remaining 62.6%, either the desired anchorage had been obtained at the time of failure or the orthodontist used an alternative source of anchorage to complete the case.

Table 16 Audit results against standards

	Data	Standard	Yes	No	Standards met
BASELINE DATA					
Was written information on procedure given to patient?	Y/N	100%	91.7%	8.3%	**No**
Documented discussion re procedure & risks	Y/N	100%	90%	10%	**NO**
Signed consent form present	Y/N	100%	82.6%	17.4%	**NO**
Point of insertion	Maxilla/mandible Buccal/lingual		80.8%/19.2% 86.4%/13.6%		
Was local anaesthesia used?	Y/N		98.9%	1.1%	
Was a flap raised / incision made?	Y/N		8.1%	91.9%	
Was drilling with a pilot drill* performed?	Y/N		4.3%	95.7%	
Was drilling with a bur performed?	Y/N		10.5%	89.5%	
Was a stent used to aid placement?	Y/N		12.4%	87.6%	
Was the TAD loaded immediately?	Y/N		79%	21%	

	Data	Standard	Yes	No	Standards met
FOLLOW-UP DATA					
Screw replaced following loss or removal?	Y/N		9%	91%	
Screw lost or removed before completion of anchorage period?	Y/N	<20%	22.1%	77.9%	**NO**
Anchorage required provided by screw without adverse effects?	Y/N	70%	67.6%	32.4%	**No**
ADVERSE EFFECTS					
Infection / inflammation around screw resulting in loss/removal?	Y/N	<20%	5.6%	94%	**Yes**
Damage to neighbouring teeth	Y/N	0%	0.7%	99.3%	**No**

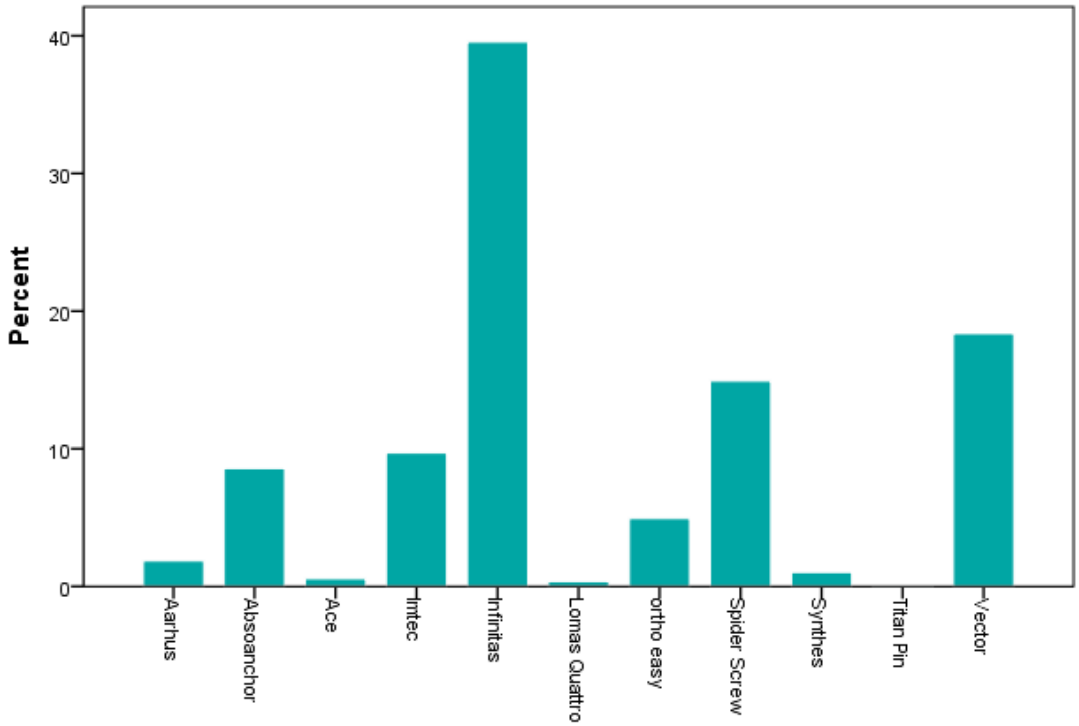


Figure 43 Distribution of TADs according to system

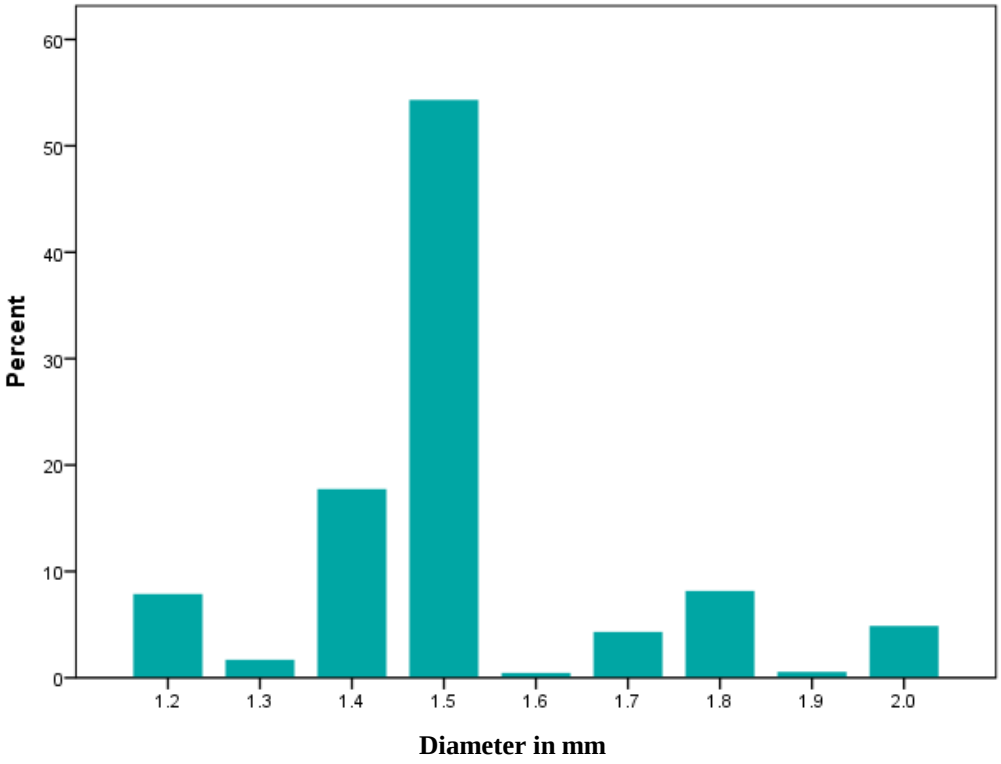


Figure 44 Distribution of TADs according to diameter

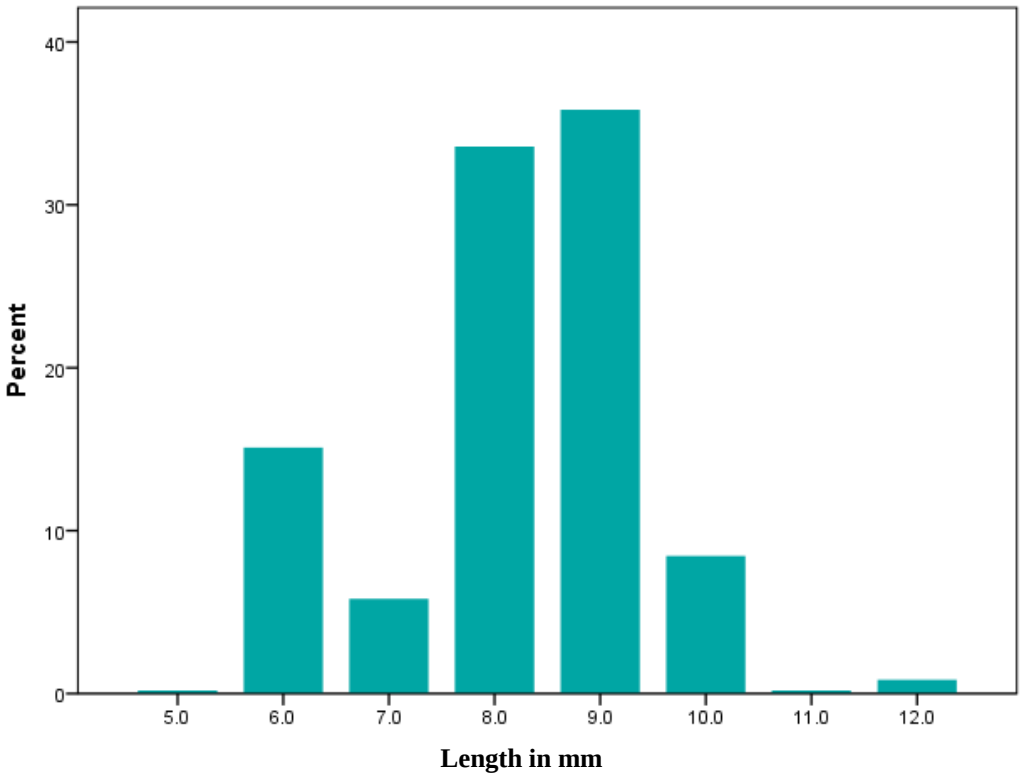


Figure 45 Distribution of TADs according to length

6.3.2 Time to failure data

The average duration for electively removed TADs was 349.7 days (SD 261.9). Of these, 42.8% stayed in situ for more than 1 year. The average duration for failed TADs was 112 days (SD 150). Among failed TADs, 25.4% were removed in the first month and 18.9% were removed in the second month.

6.3.3 Factors associated with failure

Variables were examined for any association with TAD failure. There was no association between failure and age at placement, immediate loading, length or diameter of TAD. However, there was a lower failure rate (22.5%) in the maxilla when compared to the mandible (31.1%, chi-squared P = 0.011). Participants were deemed to be high volume operators if they placed 15 TADs or more with complete insertion and outcome data. Participants in the high volume group (n = 20) placed 854 TADs, and the failure rate was 20.7% (178/854), while the low volume group (n = 51) placed 218 TADs and the failure rate was 37.1% (81/218). This positive effect of clinical experience was statistically significant (chi squared, P = 0.000).

10.4 Discussion

The most frequent piece of missing information in the clinical documentation was a consent form specifically recording TADs as part of treatment. This could have been due to an understanding of some participants that the overall orthodontic treatment consent is sufficient, without the need for a separate consent form or specific entry for TADs. However, NIHCE guidance recommends providing a specific consent form when placing a TAD.

A total of 53.2% of TADs were placed in the upper buccal segment, either between the upper first and second molar or more frequently, between upper second premolar and upper first molar. This would seem to indicate that the most common uses of TADs are for incisor or canine retraction, molar distalisation or buccal segment intrusion.

In this audit, the national failure rate (24.2%) is greater than the failure rate reported previously in systematic reviews [13.5% (Papageorgiou et al., 2012) and 16.4% (Schatzle et al., 2009)] but within the range reported in local audits,

including 20% (Mistry and Cousley, 2009), 10% (Cousley, 2011) and 47% (Barber and Morris, 2014) This difference in failure rate could be explained by the fact that data presented here were collected from 71 different sites, where the participants have variable experience in using TADs, whereas in other reports data usually represent the practice of a few experienced operators. This is supported by the finding that low volume operators had a higher failure rate, and in this study the high volume operators had a failure rate closer to that in previously published studies. Following detailed protocols in research studies may also contribute to the higher success rate of TADs in these studies, while audit data is more likely to reflect the real world current practice.

Failure rate was significantly higher in the mandible (31.1%) than in the maxilla (22.5%), which agrees with other studies (Papageorgiou et al., 2012, Cheng et al., 2004, Park et al., 2006a, Chen et al., 2006). This difference in success rate may explain the greater popularity of using TADs in the maxilla (866 TADs) compared to mandible (206 TADs) as well as the differences in clinical use where placing TADs in the mandible is often more difficult.

Temporary anchorage devices, which did not fail, on average were in place for 349.7 days. Schatzle et al. (2009) in their systematic review found that average loading time ranged from 120 days to more than 1 year, which is consistent with the findings in this study. Of the TADs that failed, 44.3% had failed or were removed in the first 2 months after initial placement, most frequently due to excess mobility. This would indicate that if a TAD is going to fail, it is most likely to do so soon after insertion.

Data collection for this self-reporting project depended on participants' subjective judgement. To limit the effects of this subjectivity, clear explanations of the data entry choices were embedded as notes in the online form. Another limitation of this project is that although this audit was designed to cover all types of temporary anchorage devices, all collected data related to miniscrews. This could be due to orthodontist's preference for using miniscrews over other types of TADs, such as onplants or mini-plates. Some two-thirds of participants in this audit were based in secondary care in a hospital setting. This does not reflect the overall balance of BOS membership, and may therefore reflect the greater opportunity for hospital-based

practitioners to participate in audit, or may indicate that TAD usage is greater in this sector.

The audit standards were set in 2007 and advances in TAD design and clinical applications since then would suggest that the TAD Audit standards currently recommended should be revised in the light of published data, to provide a more realistic expectation of how TADs should be expected to perform in current clinical practice.

10.5 Conclusion

This report of the BOS TAD audit data from 1st January 2008 to 1st November 2013 shows that nationally, the following audit standards are being achieved:

1. Infection/inflammation around the screw resulting in loss or removal in 5.6% of the cases met the standards of being below 20%.

However, the following audit standards are not being achieved:

1. written information on procedure was given to the patient in 91.7% of cases, while the standard is 100%;

2. documented discussion regarding procedure and risks was available in 90% of cases, while the standard is 100%;

3. a signed consent form was present in the patient record in 82.6% of cases, while the standard is 100%;

4. anchorage was provided without adverse effects in 67.6% of cases, while the standard is greater than 70%;

5. screws lost or removed before completion of the anchorage period occurred in 24.2% of cases, while the standard is less than 20%; and

6. damage to neighbouring teeth occurred in 0.7% of cases, where the standard is 0%.

We would make the following recommendations for clinical audit and clinical practice:

1. audit standards should be reviewed in the light of new data and clinical practice as TADs become increasingly a part of routine clinical practice. This should include reviewing the requirement for separate recording of consent;

2. operators or units with failure rates higher than the national average of 24% should review their clinical procedures;

3. low volume operators or units should in particular, monitor failure rates as these are likely to be greater than the national average and

4. national audit with annual reports should continue to allow individual operators and units to make ongoing comparisons with national data.

Chapter 7. Aims and objectives.

What is the most effective method for providing orthodontic anchorage? A Randomised Clinical Trial of Headgear, AbsoAnchor mini-screws and Palatal arch (HAP Study).

7.1 Introduction

This is a multi-centre prospective randomised parallel clinical trial of miniscrews, transpalatal arch and headgear. The study was funded by the British Orthodontic Society Foundation (08/S1401/45).

7.2 Aim

The aim of this trial was to assess the anchorage effectiveness of miniscrews, transpalatal arches and headgear.

7.3 Objectives

The primary Objective

To examine whether there is any difference between miniscrews, transpalatal arch and headgear with regard to anchorage reinforcement.

The secondary objectives

To examine if there is any difference between miniscrews, transpalatal arch and headgear with regard to

- Treatment process (duration of treatment, duration of each visit, number of visits, patient cooperation, smoking status) from data collection sheets
- Anchorage device failure from data collection sheets
- Patient experience from questionnaires

7.4 Null hypotheses

- There is no difference in treatment process between using AbsoAnchor miniscrews , transpalatal arch or Headgear to reinforce anchorage
- There is no difference in treatment outcome between using AbsoAnchor miniscrews , transpalatal arch or Headgear to reinforce anchorage
- There is no difference in the patient's experience between using AbsoAnchor miniscrews , transpalatal arch or Headgear to reinforce anchorage

Chapter 8. Subjects and methods

8.1 Inclusion criteria

Patients attending participating departments that met the following criteria:

- In the permanent dentition.
- Having a malocclusion requiring fixed appliance therapy with premolar extractions in the upper arch.
- Assessed as requiring an additional form of anchorage (i.e. treatment requires mid-arch extraction plus an additional form of anchorage).

8.2 Exclusion criteria

Patients were excluded for the following reasons:

- Craniofacial syndrome or cleft lip and/or palate.
- Medical contraindication to use of miniscrews (systemic steroid tablets, insulin dependent diabetes mellitus, haematological disorders, require antibiotic cover for invasive dental procedures, allergy to local anaesthetic).

8.3 Sample size

The sample size calculation was set to detect 2 mm of anchorage loss between the trial groups. A one way analysis of variance with a power of 90% and an alpha 0.05 would need a sample of a minimum 36 participants (12 in each group). To compensate for 20% dropouts, a further 9 participants would be needed .The final sample was 45 participants (15 in each group).

8.4 Centres involved

The study was conducted in nine centres in the United Kingdom. Dundee Dental Hospital, The Royal London Dental Hospital, Charles Clifford Dental Hospital, Countess of Chester NHS Foundation Trust, Kent and Canterbury Hospital, Trafford General Hospital and Dumfries and Galloway Royal Infirmary.

8.5 Enrolment of participants

Patients who satisfied the eligibility criteria for the study were invited to participate in the study by the clinician who would perform the orthodontic treatment. The study was explained verbally to the patients and the parents and they were given an information sheet in lay language (Appendix 4). The patients and the parents who agreed to take part in the study both signed a consent form (Appendix 5). Those who declined to participate in the study still received the orthodontic treatment based on the clinician's judgment.

8.6 Randomisation

The restricted randomisation sequence was performed using software ALEA (https://nl.tenalea.net/amc/ALEA/Login.aspx) which was developed via Trans European Network for Clinical Trials. When the suitable patient had been identified, the researcher would login to the software online system and enter the patient's information in the trial site. Provided that the patient and the parent had signed the consent form, the researcher would complete an online randomisation form. Following that, a confirmation email would be sent to the researcher with an identification number and which group was the patient randomised to. In addition, the chief investigator and trial coordinator would receive e-mail notification outlining the details of the form, but without revealing the treatment allocation. Once the randomisation process was completed, the identification number was recorded on the front of a study file that was specified for every participant in the trial. This file contained 3 questionnaires (Appendices 6, 7 and 8) with 3 opaque envelopes, flowchart of the trial (Appendix 9), and treatment process logbook (Appendix 10).

8.7 Blinding

Blinding the operator and the patients was not possible due to the visibility of orthodontic treatment. However, the data analyser was blinded from the treatment allocation through anonymising the data collection forms and questionnaires. In addition, dental models were made after the molars band were removed. In cases

where miniscrews were used, the signs of miniscrews were removed from the model prior to scanning.

8.8 Interventions

Participants were randomly assigned to one of the study groups; AbsoAnchor miniscrews, transpalatal arch and headgear.

8.8.1 AbsoAnchor Miniscrews

a. Direct bonded pre-adjusted 0.022" X 0.028" edgewise appliance with an MBT prescription.
b. Upper mid-arch extraction.
c. Placement of a 7mm long, 1.2 diameter tapered AbsoAnchor mini-screw (SH1312-07) in each side of the maxilla between the second premolar and first molar:
    i. Placement was done in the first visit (4-6 weeks) after bond up.
    ii. On the day of placement, a laceback was placed attaching the mini-screw to the canine bracket on each side.

d. Upper second molars were excluded from the bond up initially, but were bonded at the finishing stage if needed.
e. One of two archwire sequences were used according to the individual case and to the operator's discretion:
    i. Round nickel titanium, rectangular nickel titanium, rectangular stainless steel, finishing archwire
    ii. Round nickel titanium, round stainless steel, rectangular stainless steel, finishing archwire.
f. Operator's normal method of archwire ligation was used (modules or wire ligation, not self-ligating brackets).
g. Class 2 elastics were used at the operator's discretion.

8.8.2 Transpalatal arch

a. A laboratory made trans-palatal arch in 1.0mm diameter stainless steel wire with the loop facing anteriorly.
b. Upper mid-arch extraction.

c. Direct bonded pre-adjusted 0.022” X 0.028” edgewise appliance with an MBT prescription.
d. Upper second molars were excluded from the bond up initially, but were bonded at the finishing stage if needed.
e. One of two archwire sequences were used according to the individual case and to the operator’s discretion:
    i. Round nickel titanium, rectangular nickel titanium, rectangular stainless steel, finishing archwire.
    ii. Round nickel titanium, round stainless steel, rectangular stainless steel, finishing archwire.
f. Operator’s normal method of archwire ligation was used (modules or wire ligation, not self-ligating brackets).
g. Class 2 elastics were used at the operator’s discretion.

8.8.3 Headgear

a. High pull safety headgear to first molar bands:
    i. Outer arms should be turned up to the level of the trifurcation of the first molar.
    ii. Force magnitude: 250-300 gm per side.
    iii. Force duration: 12 hours per day for 6 months, after which continuation of headgear will be at the operator’s discretion.
b. Upper mid-arch extraction.
c. Direct bonded pre-adjusted 0.022” X 0.028” edgewise appliance with an MBT prescription.
d. Upper second molars were excluded from the bond up initially, but were bonded at the finishing stage if needed.
e. One of two archwire sequences were used according to the individual case and to the operator’s discretion:
    i. Round nickel titanium, rectangular nickel titanium, rectangular stainless steel, finishing archwire.
    ii. Round nickel titanium, round stainless steel, rectangular stainless steel, finishing archwire.
f. Operator’s normal method of archwire ligation was used (modules or wire ligation, not self-ligating brackets).
g. Class 2 elastics were used at the operator’s discretion.

8.9 Protocol deviation

Individual patients could be withdrawn from the study if there was;

1. Failure of the anchorage system, defined as follows:
   a) Repeated loss of anchorage device
   b) Failure to wear headgear
   c) Adverse tissue reaction requiring removal of anchorage device
   d) Loss of anchorage jeopardizing successful treatment outcome determined by molar relationship worsening by ½ unit or more from start of treatment.
2. Patient related factors:
   a) Poor oral hygiene: treatment will be stopped according to normal orthodontic protocol and records will be taken at the end of treatment.
   b) Poor attendance: treatment will be stopped according to normal orthodontic protocol and records will be taken at the end of treatment.
   c) Patient moves away from trial site: withdrawn from study, no need for records.
3. One method or operator exhibiting a non-acceptable and particularly high failure rate.

Patient's emergency visits were dealt with by a clinician who was a part of the study when possible. When it is not possible, arrangements were made for the patient to be seen by another clinician.

8.10 Outcomes measures

The primary outcome

Mesial movement of the upper molar measured in millimetres by digital study models.

The secondary outcome

- Treatment process (duration of treatment, duration of each visit, number of visits, patient cooperation, smoking status) from data collection sheets
- Anchorage device failure from data collection sheets
- Patient experience from questionnaires

8.11 Data collection

8.11.1 Times points

Data were collected in the following time points:

T1- Baseline, at commencement of treatment

T2 - Each treatment visit

T3 - At six months after treatment started

T4 - At the end of Anchorage:

T5 - End of active treatment

8.11.2 Data collected

1. Upper and lower accurate study models to be digitised by 3D laser scanner at (T1, T5)
2. Patient questionnaire "Before Treatment" at (T1)
3. Intra and extra-oral photographs at (T1,T5)
4. Duplicate of upper dental model with upper molar bands removed at (T3,T4)
5. Intra-oral photographs only at (T3)
6. Patient questionnaire 2: 'Smiles Better' brace experience at (T3)
7. Patient questionnaire "After treatment" at (T5)
8. Treatment process (length of visit , patient cooperation, procedure performed, soft tissue reaction related to anchorage device, smoking status, adverse even assessment recording and reporting) at each visit (T2)

8.11.3 Questionnaires

Questionnaires were completed by participants at T1, T3, and T5. "Before treatment" and "After treatment" questionnaires were meant to determine the participant's views on the orthodontic treatment. "Smile better" questionnaire was meant to determine the participant's experience during orthodontic treatment. These questionnaires were used before by O'Brien and his colleagues in their randomised clinical trial on Class II treatment (2003) however, they did not report if these Questionnaires had been validated before. A current PhD student at the University of Dundee, Yassir Alyassir, has validated the questionnaires. The validated questionnaires are more related to fixed appliances while the ones used by O'Brien

were more related to functional appliance treatment. However, the questionnaires used in this trial were the original questionnaires developed by O'Brien et al (2003).

8.11.4 3D model analysis

8.11.4.1 Model scanning

The study models were digitised using the R700 scanner (www.3shape.com). This equipment uses non-destructive laser beam. It consists of a platform to support the models, two high-resolution digital cameras and laser beam to capture the image (Figure 46, 47). To ensure the complete coverage of the model, the platform where the model is placed is automatically rotated during the process of scanning. The image is produced through capturing points on the model then organizing them in a triangular shape forming a point cloud. This point cloud produce a polygon mesh image and is saved as an STL file (stereolithography) (Figure 48). The mesh image is then converted to a solid colour (Fig 49). All digital models then were viewed and manipulated within the software Rapidform 2006 (INUS Technology and Rapidform Inc, Seoul, Korea).

Figure 46 3Shape R700 scanner

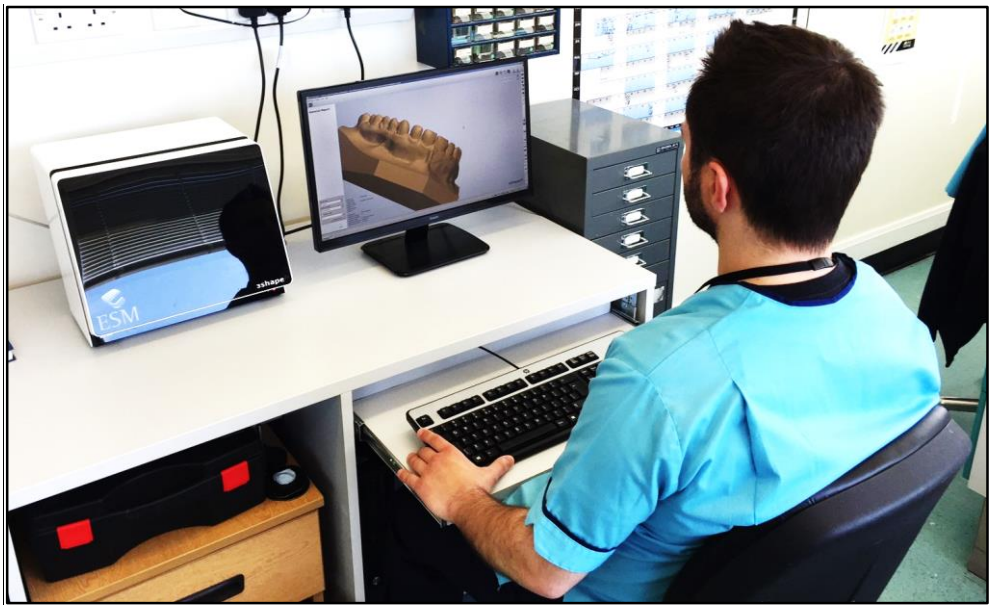


Figure 47 3Shape R700 scanner, University of Dundee, Dental School.

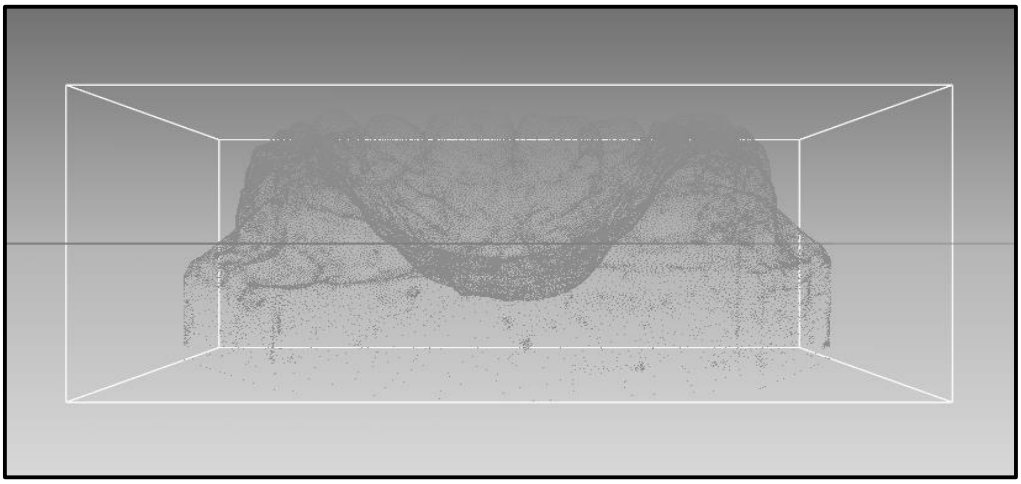


Figure 48 Polygon mesh image

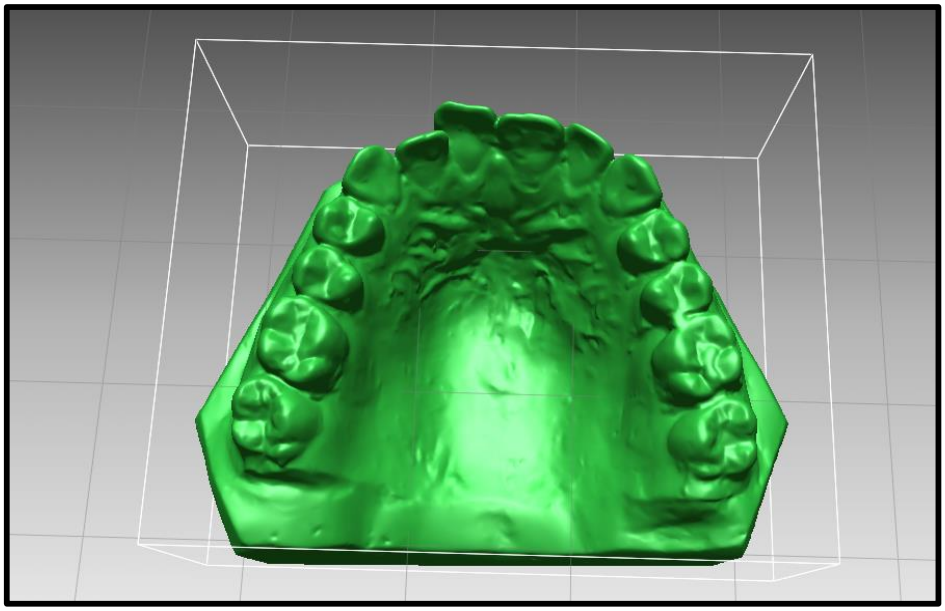


Figure 49 Occlusal view of the digital model

8.11.4.2 Molar movement measurements

The measurements were obtained by performing the following steps:

1. Assign different colours to the models (e.g. green= pretreatment model and red= mid-treatment model)
2. Orientation of the models to be parallel to bottom border of the screen.
3. Superimposition of the models then was performed with the use of the following method
   - Initial superimposition achieved through identifying medial and lateral ends of palatal rugae on the first model and the corresponding ends on the other model (Figure 50 and 51).
   - Regional superimposition where mushroom-shaped region was painted on both models (Figure 52 and 53).

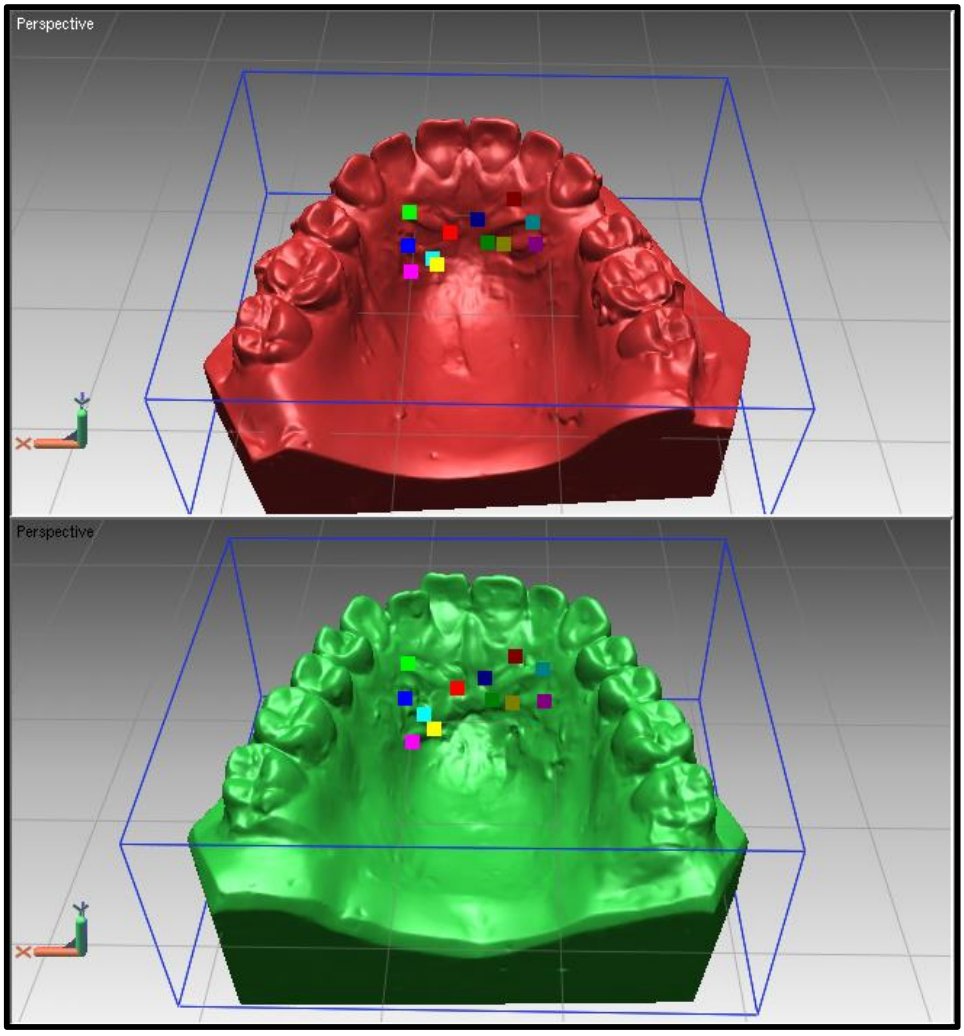


Figure 50 Land marks identification for Initial superimposition in both models

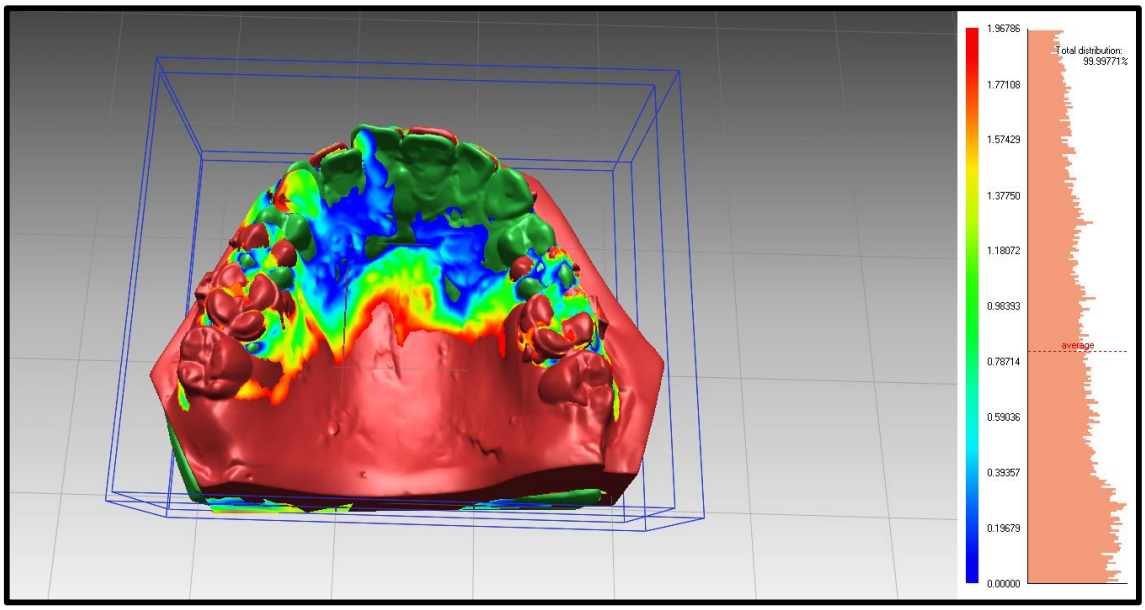


Figure 51 Initial superimposition performed

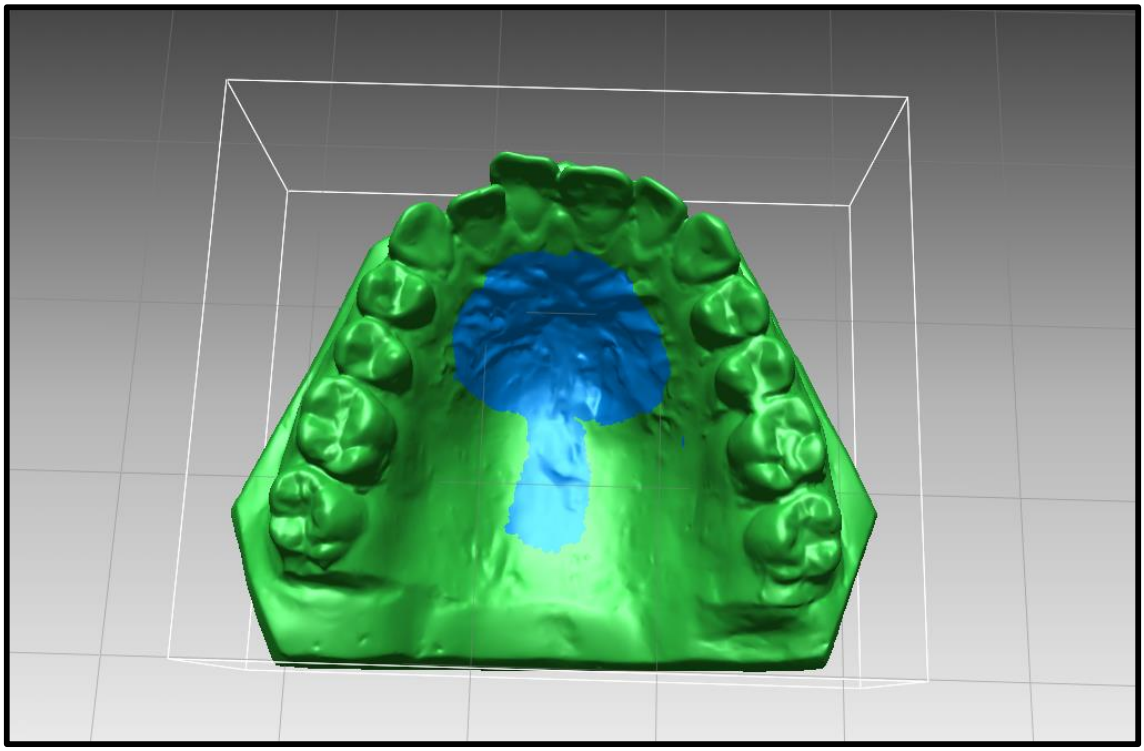


Figure 52 Painting mushroom-region

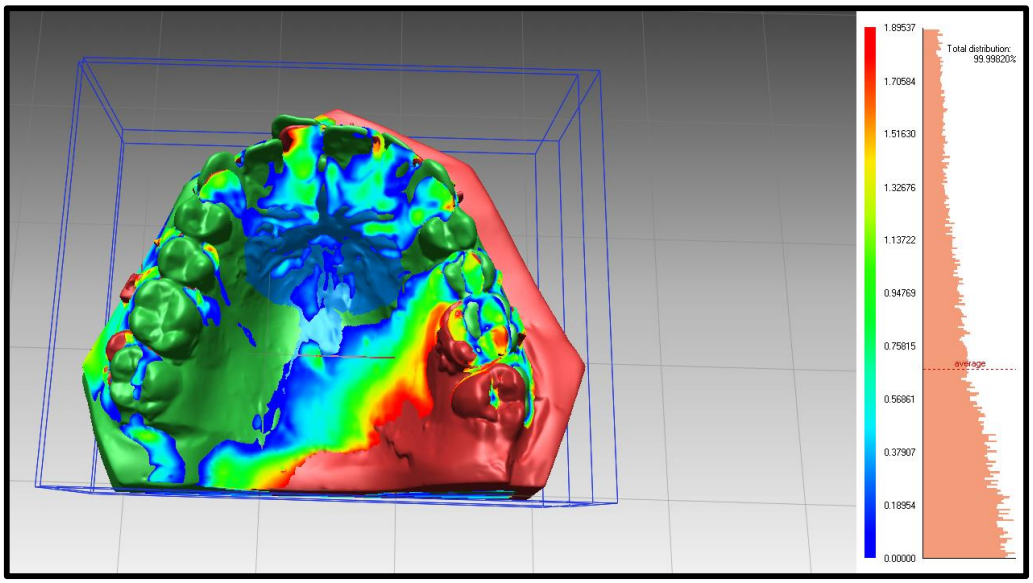


Figure 53 Regional superimposition

4. After the superimposition, shells of the first molars in both sides were identified through highlighting the whole crowns (Figure 54). This was repeated for the corresponding model.

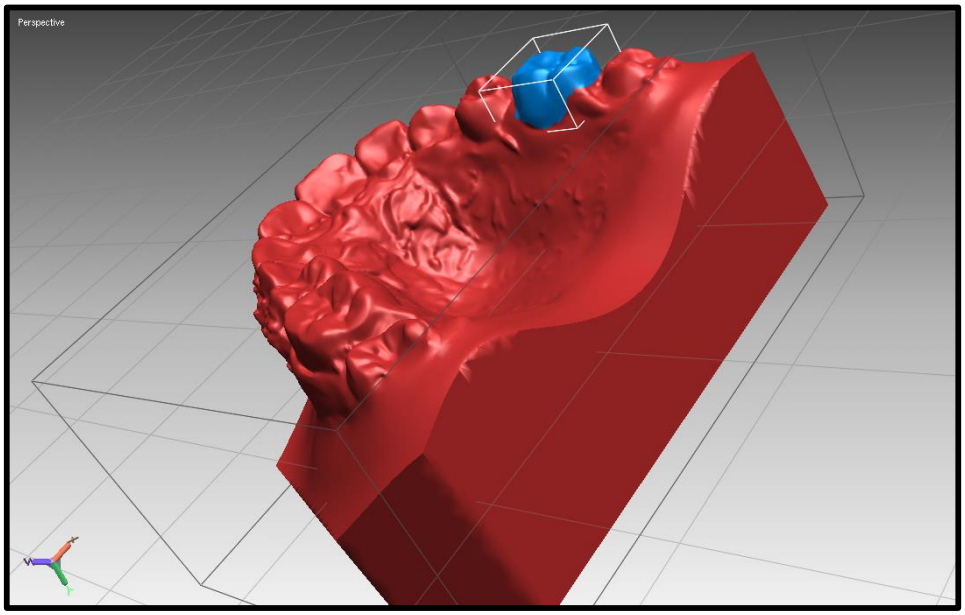


Figure 54 The crown of the first molar painted

5. Then, the centre of mass of both molars were calculated for both first molar shells (Figure 55).

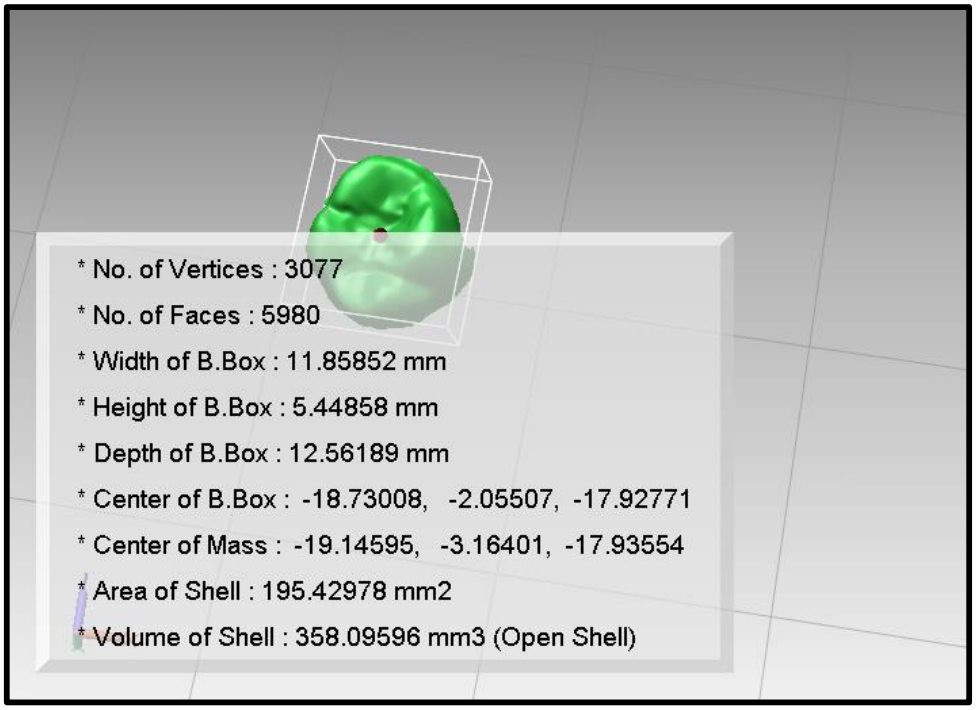


Figure 55 Centre of mass

6. Finally, the distance between the centres of mass is computed on the superimposed models (Figure 56).

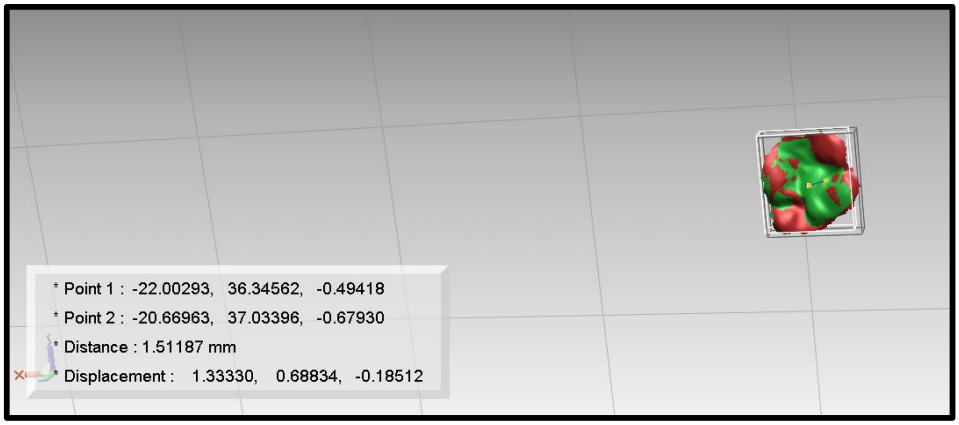


Figure 56 The distance between the two centres of mass was calculated

8.12 Statistical Analysis

In this randomised clinical trial, the anchorage loss was measured by assessing the mesial movement of the molars as the primary outcome. The mesial movement of the molars was measured in millimetres on superimposed scans of the start of the treatment and mid-treatment study models. To assess the normality of the data, a Shapiro-Wilk test was used. If data were normally distributed, then parametric tests were performed. The data were transformed to normal distribution if found to be not normally distributed by taking the log of the data. Descriptive statistics were performed to summarize the data at the start and finish time points of the trial. The comparison between the three groups (Headgear, TPA and Miniscrews) was conducted using the analysis of variance (ANOVA). The mean difference in the primary outcome between the three groups was calculated and the 95% confidence interval was computed. The categorical data were tested using chi-square. The analyses were performed using SPSS version 22 (SPSS Inc., Chicago IL).

To assess the intra-examiner reliability for the measurements of the primary outcome, a random sample of ten 3D scans were measured for the second time by the author (FA). The superimposition and measurement of right and left molars was repeated and compared against the original measurements. Intra class correlation (ICC) and Bland and Altman plots were used to assess the agreement between the repeated measurements.

Chapter 9. Results

9.1 The study participants and data collected

In the 9 centres of the trial, 54 patients met the inclusion criteria. The number of the patients who refused to participate was 12 (Figure 57). Only 43 patients were randomised to one of the trial arms. The final number of randomised patients was 42. Tables 17 and 18 present the frequency and distribution of collected data according to the centre and according to the treatment group.

Table 17 Data distribution according to treatment group

Source of data collected	Transpalatal arch	Miniscrews	Headgear	Sample analysed	Randomised	Missing
Demographic data	14	12	17	43	43	0
Start of treatment study models	6	9	13	28	43	15 (35%)
After 6 months of treatment study models	6	5	9	20*	43	22(51%)
At the end of anchorage study models	4	2	3	9	43	34(79%)
At the end of treatment study models	3	8	8	19	43	24(56%)
" Before treatment" questionnaire	6	9	10	25	43	18(42%)
" Smile better" questionnaire	5	6	9	20	43	23 (53%)
" After treatment" questionnaire	3	5	7	15	43	28(65%)
Treatment process of every visit	5	2	8	15	43	28(65%)

* One case were eliminated because of scanning error

Table 18 Data collected according to trial centre

Source of data collected	1	2	3	4	5	6	7	8	9
Demographic data	10	5	3	1	1	3	6	9	2
Start of treatment study models	10	0	0	1	0	3	4	9	2
After 6 months of treatment study models	9	0	0	1	0	3	2	4	1
At the end of anchorage study models	8	0	0	0	0	0	0	0	0
At the end of treatment study models	8	0	0	0	0	1	3	7	0
" Before treatment" questionnaire	10	1	0	1	0	2	0	8	1
" Smile better" questionnaire	10	1	0	1	0	2	0	4	1
" After treatment" questionnaire	9	1	0	0	0	2	0	9	1
Treatment process of every visit	9	0	0	1	0	2	0	1	1
Sample analysed	10	1	0	1	0	3	3	9	1
Randomised	10	5	5	1	1	3	6	9	3
Missing	0	5 (100%)	5 (100%)	0	1 (100%)	0	3 (50%)	0 (100%)	1 (50%)

CONSORT 2010 Flow Diagram

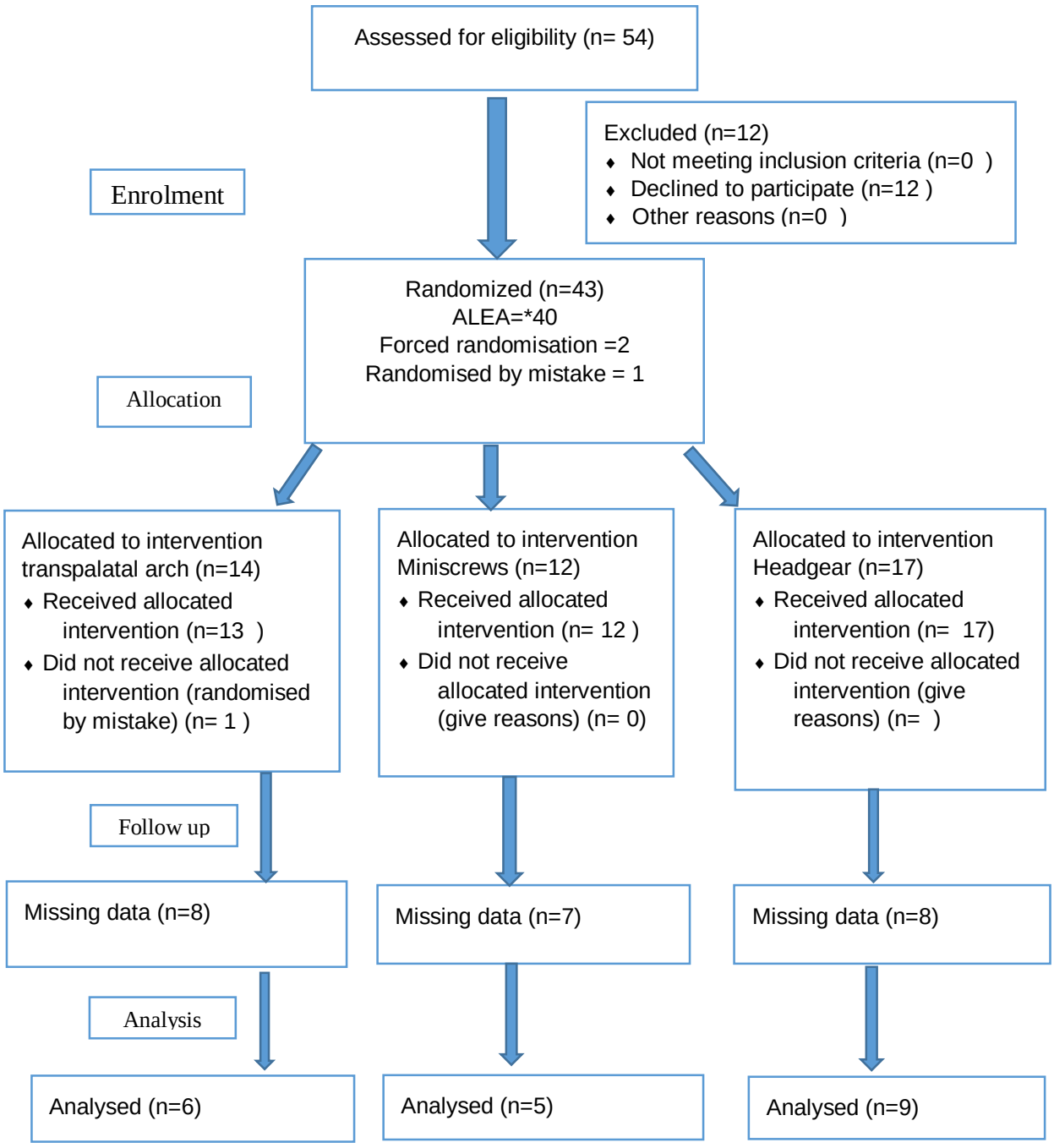


Figure 57 CONSORT diagram showing the flow of participants.

9.2 Baseline characteristics of the sample

The descriptive statistics of the age is shown in Table 19.

Table 19 Descriptive statistics of age

Variable	Miniscrews	Headgear	TPA	Overall mean
Age (mean in years)	15.3	14.3	15.08	14.8

9.3 Molar movement as measured on digital models

9.3.1 Normal distribution

The data were examined for normality of distribution using a Shapiro-Wilk test on the residuals of variables (Table 20).

Table 20 Shapiro-Wilk test for normality for the molar movement

Variable	Group	Shapiro-Wilk test		
		Statistic	df	Sig.
Left molar measurements (Mid-treatment)	Transpalatal arch	.998	3	.926
	Miniscrews	.849	4	.222
	Headgear	.863	5	.238
Right molar movement (Mid-treatment)	Transpalatal arch	.984	3	.761
	Miniscrews	.956	4	.754
	Headgear	.806	5	.090
Left molar movement (End of treatment)	Transpalatal arch	.897	3	.375
	Miniscrews	.770	4	.058
	Headgear	.983	5	.948
Right molar movement (End of treatment)	Transpalatal arch	.961	3	.621
	Miniscrews	.813	4	.128
	Headgear	.923	5	.551

9.3.2 Mean and standard deviation

The mean and standard deviation of molar mesial movement as measured on the superimposed models is presented in Table 21 for mid-treatment changes and in Table 22 for end of treatment changes for the right and the left upper molars. The mean of the left molar movement that was measured in the middle of the treatment

in headgear group was larger than the mean movement in miniscrews and transpalatal arch group. For the right molar, the mean of the molar movement was larger in transpalatal arch group in comparison with headgear and miniscrews group. The measurements of mean molar movement at the end of treatment was larger in headgear group than miniscrews and transpalatal arch groups.

Table 21 Measurement of molar movement (mid treatment models)

Molar movement	Transpalatal arch (N=6)	Miniscrews (N=5)	Headgear (N=9)
Upper left molar	0.95 (1.532)	0.87 (1.32)	1.85 (2.312)
Upper right molar	1.23 (0.439)	0.39 (0.84)	0.655 (1.088)

Table 22 Measurement of molar movement (End of treatment)

Molar movement	Transpalatal arch (N=4)	Miniscrews (N=7)	Headgear (N=8)
Upper left molar	2.56(1.47)	3.70 (1.53)	5.16 (1.996)
Upper right molar	1.76 (2.55)	3.01 (2.54)	4.65 (1.992)

9.3.3 Comparison of the mean molar mesial movement between Transpalatal arch, miniscrews and headgear

ANOVA test revealed that there was no statistical difference between the three groups in regards to the molar mesial movement (Table 23). The test was performed on data collected in the middle of treatment and end of treatment time points for the right and left upper molars.

Table 23 ANOVA test to compare the mean of molar mesial movement between the groups

Variable	Sum of Squares	df	Mean Square	F	Sig. (ANOVA)
Left molar measurements (Mid-treatment)	4.346	2	2.173	.618	.551
Right molar measurements (Mid-treatment)	2.085	2	1.042	1.332	.290
Left molar measurements (End of treatment)	18.161	2	9.081	2.900	.084
Right molar measurements (End of treatment)	20.250	2	10.125	1.793	.198

9.3.4 Reliability test of the measurements

The Interclass correlation (ICC) was 0.935 (95% IC, 0.74-0.98) for the upper left molar and 0.976 (95% CI, 0.904-0.994) for the upper right molar. This is considered a very high level of reliability between the two measurements. The Bland and Altman analysis showed agreement between the two set of measurements (Figure 58 and 59).

Table 24 Intra-examiner reliability was assessed with ICC

Tooth movement differences (Mid treatment)	Cronbach's Alpha	Interclass correlation	95% CI		Sig.
			Lower limit	Upper limit	
Upper left molar	0.935	0.935	0.74	0.98	.000
Upper right molar	0.976	0.976	0.904	0.994	.000

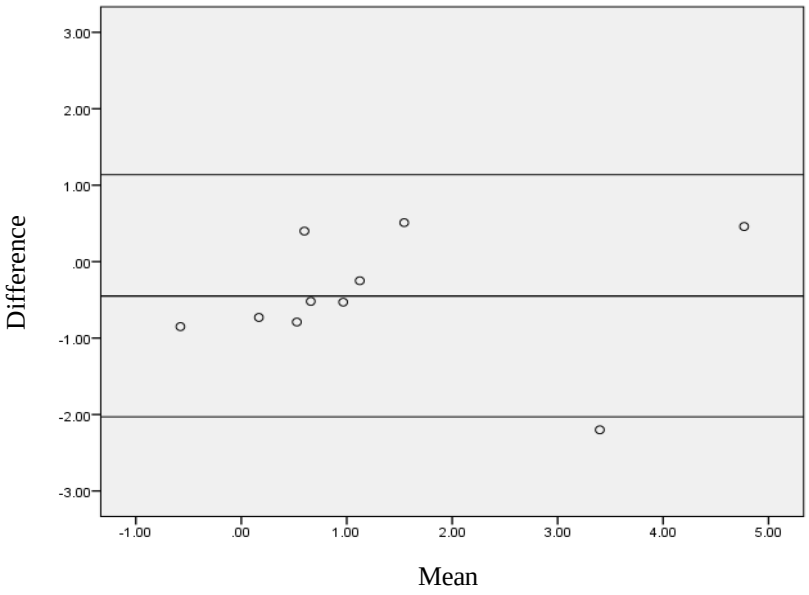


Figure 58 Bland and Altman for the measurements for the left molar

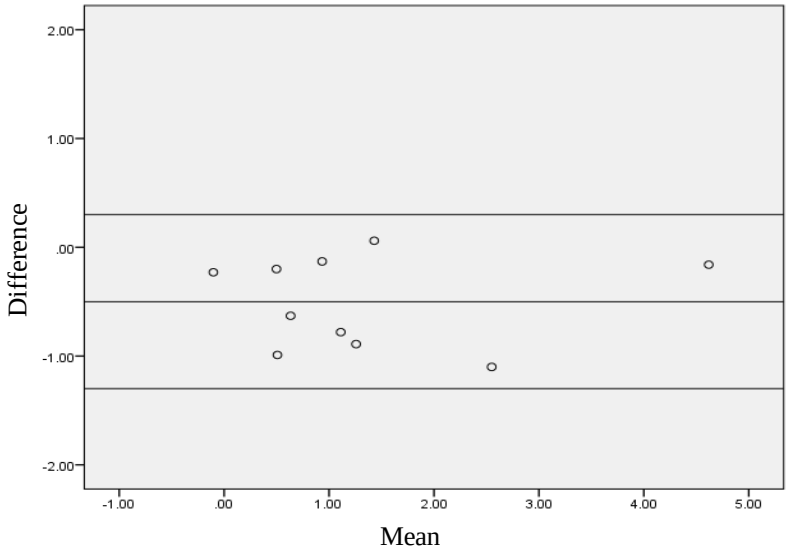


Figure 59 Bland and Altman for the measurements of the right molar

9.4 Secondary outcomes

9.4.1 Patients views on treatment before start of the treatment

The frequency distribution and the percentage of the answers to the “Before Treatment" questionnaire for the total sample are shown in Tables 25 and for the three groups in Tables 26-28.

Table 25 Patients views on treatment before start of the treatment (Total sample)

Total sample							
Reason for orthodontic treatment	**Number**	**Missing**	**Valid**	**Not a reason 1**	**2**	**3**	**Very much a reason 4**
To make my smile nicer	43 (100%)	18 (41.9%)	25 (58.1%)	0	3 (12%)	4 (16%)	18 (72%)
To help me chew food better	43 (100%)	18 (41.9%)	25 (58.1%)	10 (40%)	7 (28%)	4 (16%)	4 (16%)
To make my family happy	43 (100%)	18 (41.9%)	25 (58.1%)	15 (60%)	5 (20%)	2 (8%)	3 (12%)
To help me with my schoolwork	43 (100%)	19 (44.2%)	24 (55.8%)	19 (79.2%)	3 (12.5%)	1 (4.2%)	1 (4.2%)
To make my teeth look nicer	43 (100%)	18 (41.9%)	25 (58.1%)	1 (4%)	0	2 (8%)	22 (88%)
To help me breathing	43 (100%)	18 (41.9%)	25 (58.1%)	20 (80%)	2 (8%)	2 (8%)	1 (4%)
To feel more confident	43 (100%)	19 (44.2%)	24 (55.8%)	0	3 (12.5%)	8 (33.3%)	13 (54.2%)
To help my top and bottom teeth fit together	43 (100%)	19 (44.2%)	24 (55.8%)	3 (12.5%)	6 (25%)	5 (20.8%)	10 (41.7%)
To help me speak more clearly	43 (100%)	19 (44.2%)	24 (55.8%)	13 (54.2%)	3 (12.5%)	3 (12.5%)	5 (20.8%)
To make face look better	43(100%)	19(44.2%)	24(55.8%)	3(12%)	8(32%)	8(32%)	6(24%)
To make me feel better about myself	43 (100%)	18 (41.9%)	25 (58.1%)	2 (8%)	6 (24%)	3 (12%)	14 (56%)

To keep my gum healthy	43 (100%)	18 (41.9%)	25 (58.1%)	8 (32%)	8 (32%)	5 (20%)	4 (16%)
To make me healthier	43 (100%)	18 (41.9%)	25 (58.1%)	8 (34.8%)	8 (34.8%)	4 (17.4%)	3 (13%)
To keep me from losing teeth in the future	43 (100%)	18 (41.9%)	25 (58.1%)	7 (28%)	9 (36%)	3 (12%)	6 (24%)
To help me make friends	43 (100%)	18 (41.9%)	2 5(58.1%)	17 (68%)	6 (24%)	1 (4%)	1 (4%)
To keep my jaw joints healthy	43 (100%)	19 (44.2%)	24 (55.8%)	6 (25%)	10 (41.7%)	3 (12.5%)	5 (20.8%)
To help my front teeth fit together	43 (100%)	18 (41.9%)	25 (58.1%)	4 (16%)	3 (12%)	7 (28%)	11 (44%)
To make me look better	43 (100%)	18 (41.9%)	25 (58.1%)	1 (4%)	4 (16%)	7 (28%)	13 (52%)
To make me feel better about going out	43(100%)	18(41.9%)	25(58.1%)	5(20%)	5(20%)	7(28%)	8(32%)
To help keep my joints from clicking	43 (100%)	18 (41.9%)	25 (58.1%)	13 (52%)	5 (20%)	4 (16%)	3 (12%))
To help my back teeth fit together	43 (100%)	19 (44.2%)	24 (55.8%)	8 (33%)	3 (13%)	6 (25%)	7 (29%)
To make it easier to get on with people	4 3(100%)	18 (41.9%)	25 (58.1%)	15 (60%)	6 (24%)	2 (8%)	2 (8%)
To make it easier to bite into food	43 (100%)	18 (41.9%)	25 (58.1%)	8 (32%)	7 (28%)	5 (20%)	5 (20%)

Table 26 Patients view of treatment before start of treatment (Transpalatal arch)

Transpalatal arch							
Reason for orthodontic treatment	**Number**	**Missing**	**Valid**	**Not a reason 1**	**2**	**3**	**Very much a reason 4**
To make my smile nicer	14 (100%)	8 (57.1%)	6 (42.9%)	0	1 (16.7%)	0	5 (83.3%)
To help me chew food better	14 (100%)	8 (57.1%)	6 (42.9%)	3 (50%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
To make my family happy	14 (100%)	8 (57.1%)	6 (42.9%)	4 (66.7%)	1 (16.7%)	1 (16.7%)	0
To help me with my schoolwork	14 (100%)	9 (64.3%)	5 (35.7%)	5 (100%)	0	0	0
To make my teeth look nicer	14 (100%)	8 (57.1%)	6 (42.9%)	0	0	0	6 (100%)
To help me breathing	14 (100%)	8 (57.1%)	6 (42.9%)	4 (66.7%)	2 (33.3%)	0	0
To feel more confident	14 (100%)	9 (64.3%)	5 (35.7%)	0	0	1 (20)	4 (80%)
Ti help my top and bottom teeth fit together	14 (100%)	9 (64.3%)	5 (35.7%)	0	0	1 (20%)	4 (80%)
To help me speak more clearly	14 (100%)	9 (64.3%)	5 (35.7%)	2 (40%)	1 (20%)	0	2 (40%)
To make face look better	14 (100%)	8 (57.1%)	6 (42.9%)	1 (16.7%)	3 (50%)	1 (16.7%)	1 (16.7%)
To make me feel better about myself	14 (100%)	8 (57.1%)	6 (42.9%)	0	1 (16.7%)	0	5 (83.3%)
To keep my gum healthy	14 (100%)	8 (57.1%)	6 (42.9%)	1 (16.7%)	3 (50%)	2 (33.3%)	0
To make me healthier	14 (100%)	8 (57.1%)	6 (42.9%)	1 (16.7%)	3 (50%)	1 (16.7%)	1 (16.7%)

To keep me from losing teeth in the future	14 (100%)	8 (57.1%)	6 (42.9%)	1 (16.7%)	3 (50%)	1 (16.7%)	1 (16.7%)
To help me make friends	14 (100%)	8 (57.1%)	6 (42.9%)	4 (66.7%)	2 (33.3%)	0	0
To keep my jaw joints healthy	14 (100%)	8 (57.1%)	6 (42.9%)	2 (33.3%)	3 (50%)	1 (16.7%)	0
To help my front teeth fit together	14 (100%)	8 (57.1%)	6 (42.9%)	0	1 (16.7%)	3 (50%)	2 (33.3%)
To make me look better	14 (100%)	8 (57.1%)	6 (42.9%)	0	0	3 (50%)	3 (50%)
To make me feel better about going out	14 (100%)	8 (57.1%)	6 (42.9%)	0	2 (33.3%)	2 (33.3%)	2 (33.3%)
To help keep my joints from clicking	14 (100%)	8 (57.1%)	6 (42.9%)	4 (66.7%)	1 (16.7%)	1 (16.7%)	0
To help my back teeth fit together	14 (100%)	9 (64.3%)	5 (35.7%)	2 (40%)	1 (20%)	1 (20%)	1 (20%)
To make it easier to get on with people	14 (100%)	8 (57.1%)	6 (42.9%)	2 (33.3%)	3 (50%)	0	1 (16.7%)
To make it easier to bite into food	14(100%)	8(57.1%)	6(42.9%)	2(33.3%)	1(16.7%)	2(33.3%)	1(16.7%)

Table 27 Patients views on treatment before start of the treatment (Miniscrews)

Miniscrews							
Reason for orthodontic treatment	**Number**	**Missing**	**Valid**	**Not a reason 1**	**2**	**3**	**Very much a reason 4**
To make my smile nicer	12 (100%)	3 (25%)	9 (75%)	0	1 (11.1%)	2 (22.2%)	6 (66.7%)
To help me chew food better	12 (100%)	3 (25%)	9 (75%)	3 (33.3%)	2 (22.2%)	3 (33.3%)	1 (11.1%)
To make my family happy	12 (100%)	3 (25%)	9 (75%)	3 (33.3%)	4 (44.4%)	1 (11.1%)	1 (11.1%)
To help me with my schoolwork	12 (100%)	3 (25%)	9 (75%)	6 (66.7%)	2 (22.2%)	0	1 (11.1%)
To make my teeth look nicer	12 (100%)	3 (25%)	9 (75%)	0	0	1 (11.1%)	8 (88.9%)
To help me breathing	12 (100%)	3 (25%)	9 (75%)	7 (77.8%)	0	1 (11.1%)	1 (11.1%)
To feel more confident	12 (100%)	3 (25%)	9 (75%)	0	1 (11.1%)	1 (11.1%)	7 (77.8%)
Ti help my top and bottom teeth fit together	12 (100%)	3 (25%)	9 (75%)	1 (11.1%)	3 (33.3%)	1 (11.1%)	4 (44.4%)
To help me speak more clearly	12 (100%)	3 (25%)	9 (75%)	5 (55.6%)	1 (11.1%)	0	3(33.3%)
To make face look better	12 (100%)	3 (25%)	9 (75%)	0	2 (22.2%)	4 (44.4%)	3 (33.3%)
To make me feel better about myself	12 (100%)	3 (25%)	9 (75%)	1 (11.1%)	0	1 (11.1%)	7 (77.8%)

To keep my gum healthy	12 (100%)	3 (25%)	9 (75%)	1 (11.1%)	4 (44.4%)	0	4 (44.4%)
To make me healthier	12 (100%)	3 (25%)	9 (75%)	3 (33.3%)	2 (22.2%)	1 (11.1%)	3 (33.3%)
To keep me from losing teeth in the future	12 (100%)	3 (25%)	9 (75%)	2 (22.2%)	3 (33.3%)	1 (11.1%)	3 (33.3%)
To help me make friends	12 (100%)	3 (25%)	9 (75%)	6 (66.7%)	2 (22.2%)	0	1 (11.1%)
To keep my jaw joints healthy	12 (100%)	4 (33.3%)	8 (66.7%)	1 (12.5%)	3 (37.5%)	0	1 (11.1%)
To help my front teeth fit together	12 (100%)	3 (25%)	9 (75%)	1 (11.1%)	2 (22.2%)	1 (11.1%)	5 (55.6%)
To make me look better	12 (100%)	3 (25%)	9 (75%)	0	2 (22.2%)	2 (22.2%)	5 (55.6%)
To make me feel better about going out	12 (100%)	3 (25%)	9 (75%)	2 (22.2%)	1 (11.1%)	3 (33.3%)	3 (33.3%)
To help keep my joints from clicking	12 (100%)	3 (25%)	9 (75%)	3 (33.3%)	1 (11.1%)	2 (22.2%)	3 (33.3%)
To help my back teeth fit together	12 (100%)	3 (25%)	9 (75%)	2 (22.2%)	2 (22.2%)	1 (11.1%)	4 (44.4%)
To make it easier to get on with people	12 (100%)	3 (25%)	9 (75%)	7 (77.8%)	1 (11.1%)	0	1 (11.1%)
To make it easier to bite into food	12 (100%)	3 (25%)	9 (75%)	3 (33.3%)	2 (22.2%)	1 (11.1%)	3 (33.3%)

Table 28 Patients views on treatments before start of the treatment (Headgear)

Headgear							
Reason for orthodontic treatment	**Number**	**Missing**	**Valid**	**Not a reason 1**	**2**	**3**	**Very much a reason 4**
To make my smile nicer	17(100%)	7(41.2%)	10(58.8%)	0	1(10%)	2(20%)	7(70%)
To help me chew food better	17(100%)	7(41.2%)	10(58.8%)	4(40%)	4(40%)	0	1(10%)
To make my family happy	17(100%)	7(41.2%)	10(58.8%)	8(80%)	0	0	2(20%)
To help me with my schoolwork	17(100%)	7(41.2%)	10(58.8%)	8(80%)	0	2(20%)	0
To make my teeth look nicer	17(100%)	7(41.2%)	10(58.8%)	1(10%)	0	1(10%)	8(80%)
To help me breathing	17(100%)	7(41.2%)	10(58.8%)	9(90%)	0	1(10%)	0
To feel more confident	17(100%)	7(41.2%)	10(58.8%)	0	2(20%)	6(60%)	2(20%)
Ti help my top and bottom teeth fit together	17(100%)	7(41.2%)	10(58.8%)	2(20%)	2(20%)	4(40%)	2(20%)
To help me speak more clearly	17(100%)	7(41.2%)	10(58.8%)	6(60%)	1(10%)	3(30%)	0
To make face look better	17(100%)	7(41.2%)	10(58.8%)	2(20%)	3(30%)	3(30%)	2(20%)
To make me feel better about myself	17(100%)	7(41.2%)	10(58.8%)	1(10%)	5(50%)	2(20%)	2(20%)
To keep my gum healthy	17(100%)	7(41.2%)	10(58.8%)	4(40%)	3(30%)	2(20%)	1(10%)
To make me healthier	17(100%)	7(41.2%)	10(58.8%)	4(40%)	3(30%)	3(30%)	0
To keep me from losing teeth in the future	17(100%)	7(41.2%)	10(58.8%)	4(40%)	3(30%)	1(10%)	2(20%)

To help me make friends	17(100%)	7(41.2%)	10(58.8%)	7(70%)	2(20%)	1(10%)	0
To keep my jaw joints healthy	17(100%)	7(41.2%)	10(58.8%)	3(30%)	4(40%)	2(20%)	1(10%)
To help my front teeth fit together	17(100%)	7(41.2%)	10(58.8%)	3(30%)	0	3(30%)	4(40%)
To make me look better	17(100%)	7(41.2%)	10(58.8%)	1(10%)	2(20%)	2(20%)	5(50%)
To make me feel better about going out	17(100%)	7(41.2%)	10(58.8%)	3(30%)	2(20%)	2(20%)	3(30%)
To help keep my joints from clicking	17(100%)	7(41.2%)	10(58.8%)	6(60%)	3(30%)	1(10%)	0
To help my back teeth fit together	17(100%)	7(41.2%)	10(58.8%)	4(44.4%)	0	4(44.4%)	1(11.1%)
To make it easier to get on with people	17(100%)	7(41.2%)	10(58.8%)	6(60%)	2(20%)	0	2(20%)
To make it easier to bite into food	17(100%)	7(41.2%)	10(58.8%)	3(30%)	4(40%)	2(20%)	0

9.4.2 Patient reviews at the end of the orthodontic treatment

The frequency distribution and the percentage of the answers to the "After Treatment" questionnaire for the total sample are shown in Tables 29 and for the three groups in Tables 30-32.

Table 29 Patient reviews of treatment after treatment had finished (Total sample)

Total sample							
Reason for orthodontic treatment	**Number**	**Missing**	**Valid**	**No better**	**A little better**	**Much better**	**Very much better**
It has made it easier to chew my food	43(100%)	28(65%)	15(35%)	5(33.3%)	5(33.3%)	3(20%)	2(13.3%)
It has made my family happier	43(100%)	28(65%)	15(35%)	5(33.3%)	3(20%)	4(26.6%)	3(20%)
It has helped me with schoolwork	43(100%)	28(65%)	15(35%)	9(60%)	2(13.3%)	1(6.7%)	3(20%)
It has made my teeth look nicer	43(100%)	28(65%)	15(35%)	0	0	4(26.6%)	11(73.3%)
It has helped my breathing	43(100%)	28(65%)	15(35%)	9(60%)	1(6.7%)	2(13.3%)	3(20%)
It has made me more confident	43(100%)	28(65%)	15(35%)	1(6.7%)	2(13.3%)	6(40%)	6(40%)
It has helped my top and bottom teeth fit together	43(100%)	28(65%)	15(35%)	0	3(20%)	3(20%)	9(60%)
It has helped me speak more clearly	43(100%)	28(65%)	15(35%)	4(26.6%)	5(33.3%)	4(26.6%)	2(13.3%)
It has made my face look better	43(100%)	28(65%)	15(35%)	1(6.78%)	2(13.3%)	6(40%)	6(40%)
It has made me feel better about myself	43(100%)	28(65%)	15(35%)	0	3(20%)	4(26.6%)	7(46.6%)

It has made my gums healthier	43(100%)	28(65%)	15(35%)	4(26.6%)	4(26.6%)	4(26.6%)	3(20%)
It has made me healthier	43(100%)	28(65%)	15(35%)	7(46.7%)	3(20%)	3(20%)	2(13.3%)
It will stop me losing teeth in the future	43(100%)	28(65%)	15(35%)	5(33.3%)	3(20%)	3(20%)	4(26.6%)
It is easier to make friends	43(100%)	28(65%)	15(35%)	8(53.3%)	1(6.7%)	4(26.6%)	2(13.3%)
It has helped to keep my jaw joints healthy	43(100%)	28(65%)	15(35%)	7(46.6%)	2(13.3%)	2(13.3%)	3(20%)
It has helped my front teeth fit together	43(100%)	28(65%)	15(35%)	1(6.7%)	2(13.3%)	6(40%)	6(40%)
It has made me look better	43(100%)	28(65%)	15(35%)	0	2(13.3%)	4(26.6%)	9(60%)
It has made me feel better about going about	43(100%)	28(65%)	15(35%)	2(13.3%)	2(13.3%)	5(33.3%)	6(40%)
It keeps my jaw joints from clicking	43(100%)	28(65%)	15(35%)	7(46.6%)	(20%)	4(26.6%)	1(6.7%)
It has helped my back teeth fit together	43(100%)	28(65%)	15(35%)	2(13.3%)	2(13.3%)	6(40%)	5(33.3%)
It has made it easier to get on with people	43(100%)	28(65%)	15(35%)	8(53.3%)	1(6.7%)	1(6.7%)	5(33.3%)
It has made it easier to bite food	43(100%)	28(65%)	15(35%)	4(26.6%)	1(6.7%)	6(40%)	4(26.6%)

Table 30 Patients review on treatment after treatment had finished (Transpalatal arch)

Transpalatal arch							
Reason for orthodontic treatment	**Number**	**Missing**	**Valid**	**No better**	**A little better**	**Much better**	**Very much better**
It has made it easier to chew my food	14(100%)	11(78.6%)	3(21.4%)	1(33.3%)	0	1(33.3%)	1(33.3%)
It has made my family happier	14(100%)	11(78.6%)	3(21.4%)	1(33.3%)	0	2(66.6%)	0
It has helped me with schoolwork	14(100%)	11(78.6%)	3(21.4%)	2(66.6%)	0	1(33.3%)	0
It has made my teeth look nicer	14(100%)	11(78.6%)	3(21.4%)	0	0	0	3(100%)
It has helped my breathing	14(100%)	11(78.6%)	3(21.4%)	2(66.6%)	0	1(33.3%)	0
It has made me more confident	14(100%)	11(78.6%)	3(21.4%)	0	0	0	3(100%)
It has helped my top and bottom teeth fit together	14(100%)	11(78.6%)	3(21.4%)	0	0	1(33.3%)	2(66.6%)
It has helped me speak more clearly	14(100%)	11(78.6%)	3(21.4%)	1(33.3%)	1(33.3%)	0	1(33.3%)
It has made my face look better	14(100%)	11(78.6%)	3(21.4%)	0	0	1(33.3%)	2(66.6%)
It has made me feel better about myself	14(100%)	11(78.6%)	3(21.4%)	0	0	0	3(100%)
It has made my gums healthier	14(100%)	11(78.6%)	3(21.4%)	0	0	3(100%)	0

It has made me healthier	14(100%)	11(78.6%)	3(21.4%)	1(33.3%)	1(33.3%)	1(33.3%)	0
It will stop me losing teeth in the future	14(100%)	11(78.6%)	3(21.4%)	1(33.3%)	0	1(33.3%)	1(33.3%)
It is easier to make friends	14(100%)	11(78.6%)	3(21.4%)	2(66.6%)	0	1(33.3%)	0
It has helped to keep my jaw joints healthy	14(100%)	11(78.6%)	3(21.4%)	1(33.3%)	1(33.3%)	1(33.3%)	0
It has helped my front teeth fit together	14(100%)	11(78.6%)	3(21.4%)	0	0	1(33.3%)	2(66.6%)
It has made me look better	14(100%)	11(78.6%)	3(21.4%)	0	0	0	3(100%)
It has made me feel better about going about	14(100%)	11(78.6%)	3(21.4%)	0	0	1(33.3%)	2(66.6%)
It keeps my jaw joints from clicking	14(100%)	11(78.6%)	3(21.4%)	1(33.3%)	0	2(66.6%)	0
It has helped my back teeth fit together	14(100%)	11(78.6%)	3(21.4%)	0	0	1(33.3%)	2(66.6%)
It has made it easier to get on with people	14(100%)	11(78.6%)	3(21.4%)	2(66.6%)	0	0	1(33.3%)
It has made it easier to bite food	14(100%)	11(78.6%)	3(21.4%)	0	0	1(33.3%)	2(66.6%)

Table 31 Patients review on treatment after treatment had finished (Miniscrews)

Miniscrews							
Reason for orthodontic treatment	**Number**	**Missing**	**Valid**	**No better**	**A little better**	**Much better**	**Very much better**
It has made it easier to chew my food	12(100%)	7(58.3%)	5(41.7%)	2(40%)	1(20%)	2(40%)	0
It has made my family happier	12(100%)	7(58.3%)	5(41.7%)	1(20%)	1(20%)	2(40%)	1(20%)
It has helped me with schoolwork	12(100%)	7(58.3%)	5(41.7%)	3(60%)	0	0	2(40%)
It has made my teeth look nicer	12(100%)	7(58.3%)	5(41.7%)	0	0	1(20%)	4(80%)
It has helped my breathing	12(100%)	7(58.3%)	5(41.7%)	3(60%)	0	1(20%)	1(20%)
It has made me more confident	12(100%)	7(58.3%)	5(41.7%)	0	1(20%)	3(60%)	1(20%)
It has helped my top and bottom teeth fit together	12(100%)	7(58.3%)	5(41.7%)	0	0	1(20%)	4(80%)
It has helped me speak more clearly	12(100%)	7(58.3%)	5(41.7%)	0	2(40%)	3(60%)	0
It has made my face look better	12(100%)	7(58.3%)	5(41.7%)	1(20%)	0	3(60%)	1(20%)
It has made me feel better about myself	12(100%)	7(58.3%)	5(41.7%)	0	1(20%)	2(40%)	2(40%)
It has made my gums healthier	12(100%)	7(58.3%)	5(41.7%)	2(40%)	1(20%)	1(20%)	1(20%)
It has made me healthier	12(100%)	7(58.3%)	5(41.7%)	2(40%)	1(20%)	2(40%)	0
It will stop me losing teeth in the future	12(100%)	7(58.3%)	5(41.7%)	1(20%)	2(40%)	1(20%)	1(20%)
It is easier to make friends	12(100%)	7(58.3%)	5(41.7%)	3(60%)	0	1(20%)	1(20%)
It has helped to keep my jaw joints healthy	12(100%)	7(58.3%)	5(41.7%)	3(60%)	0	1(20%)	1(20%)

It has helped my front teeth fit together	12(100%)	7(58.3%)	5(41.7%)	0	1(20%)	2(40%)	2(40%)
It has made me look better	12(100%)	7(58.3%)	5(41.7%)	0	1(20%)	2(40%)	2(40%)
It has made me feel better about going about	12(100%)	7(58.3%)	5(41.7%)	2(40%)	1(20%)	2(40%)	0
It keeps my jaw joints from clicking	12(100%)	7(58.3%)	5(41.7%)	2(40%)	1(20%)	2(40%)	0
It has helped my back teeth fit together	12(100%)	7(58.3%)	5(41.7%)	0	1(20%)	3(60%)	1(20%)
It has made it easier to get on with people	12(100%)	7(58.3%)	5(41.7%)	3(60%)	0	0	2(40%)
It has made it easier to bite food	12(100%)	7(58.3%)	5(41.7%)	1(20%)	1(20%)	2(40%)	1(20%)

Table 32 Patients review on treatment after treatment had finished (Headgear)

Headgear							
Reason for orthodontic treatment	**Number**	**Missing**	**Valid**	**No better**	**A little better**	**Much better**	**Very much better**
It has made it easier to chew my food	17(100%)	10(58.8%)	7(41.2%)	2(28.5%)	4(57.1%)	0	1(14.2%)
It has made my family happier	17(100%)	10(58.8%)	7(41.2%)	2(28.5%)	2(28.5%)	1(7.1%)	2(28.5%)
It has helped me with schoolwork	17(100%)	10(58.8%)	7(41.2%)	4(57.1%)	2(28.5%)	0	1(14.2%)
It has made my teeth look nicer	17(100%)	10(58.8%)	7(41.2%)	0	0	3(42.8%)	4(57.1%)
It has helped my breathing	17(100%)	10(58.8%)	7(41.2%)	4(57.1%)	1(14.2%)	0	2(28.5%)
It has made me more confident	17(100%)	10(58.8%)	7(41.2%)	1(14.2%)	1(14.2%)	3(42.8%)	2(28.5%)
It has helped my top and bottom teeth fit together	17(100%)	10(58.8%)	7(41.2%)	0	3(42.8%)	1(14.2%)	3(42.8%)
It has helped me speak more clearly	17(100%)	10(58.8%)	7(41.2%)	3(42.8%)	2(28.5%)	1(14.2%)	1(14.2%)
It has made my face look better	17(100%)	10(58.8%)	7(41.2%)	0	2(28.5%)	2(28.5%)	3(42.8%)
It has made me feel better about myself	17(100%)	10(58.8%)	7(41.2%)	0	2(28.5%)	2(28.5%)	2(42.8%)
It has made my gums healthier	17(100%)	10(58.8%)	7(41.2%)	2(28.5%)	3(42.8%)	0	2(28.5%)

It has made me healthier	17(100%)	10(58.8%)	7(41.2%)	4(57.1%)	1(14.2%)	0	2(28.5%)
It will stop me losing teeth in the future	17(100%)	10(58.8%)	7(41.2%)	3(42.8%)	1(14.2%)	1(14.2%)	2(28.5%)
It is easier to make friends	17(100%)	10(58.8%)	7(41.2%)	3(42.8%)	1(14.2%)	2(28.5%)	1(14.2%)
It has helped to keep my jaw joints healthy	17(100%)	10(58.8%)	7(41.2%)	3(42.8%)	1(14.2%)	0	2(28.5%)
It has helped my front teeth fit together	17(100%)	10(58.8%)	7(41.2%)	1(14.2%)	1(14.2%)	3(42.8%)	2(28.5%)
It has made me look better	17(100%)	10(58.8%)	7(41.2%)	0	1(14.2%)	2(28.5%)	4(57.1%)
It has made me feel better about going about	17(100%)	10(58.8%)	7(41.2%)	0	2(28.5%)	3(42.8%)	2(28.5%)
It keeps my jaw joints from clicking	17(100%)	10(58.8%)	7(41.2%)	4(57.1%)	2(28.5%)	0	1(14.2%)
It has helped my back teeth fit together	17(100%)	10(58.8%)	7(41.2%)	2(28.5%)	1(14.2%)	2(28.5%)	2(28.5%)
It has made it easier to get on with people	17(100%)	10(58.8%)	7(41.2%)	3(42.8%)	1(14.2%)	1(14.2%)	2(28.5%)
It has made it easier to bite food	17(100%)	10(58.8%)	7(41.2%)	3(42.8%)	0	3(42.8%)	1(14.2%)

9.4.3 Patients' perception of treatment (Smile better questionnaire)

The frequency distribution and the percentage of the answers to the Smile Better questionnaire for the total sample are shown in Tables 33-38 and for the three groups in Tables 39-56.

Table 33 Patients' perception of treatment in general (Total sample)

Total study sample							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	43(100%)	23(53.5%)	20(46.5%)	4 (20%)	13(65%)	2(10%)	1(5%)
Eating	43(100%)	23(53.5%)	20(46.5%)	3(15%)	12(60%)	4(20%)	1(5%)
Drinking	43(100%)	23(53.5%)	20(46.5%)	2(10%)	18(90 %)	0	0
Sleeping	43(100%)	24(55.8%)	19(44.2%)	3 (15.8%)	13(68.4%)	3(15.8%)	0
Appearance	43(100%)	23(53.5%)	20(46.5%)	12(60)	3(15%)	4(20%)	1(5%)
Teasing	43(100%)	23(53.5%)	20(46.5%)	6(35.3%)	1(64.7%)	0	0
	Number	Missing	Valid	Not at All	A little	A lot	
Sore teeth	43(100%)	23(53.5%)	20(46.5%)	5(25%)	15(75%)	0	
Sore mouth	43(100%)	24(55.8%)	19(44.2%)	6(31.6%)	12(63.2%)	1(5.3%)	
Sore rubbing	43(100%)	23(53.5%)	20(46.5%)	10(50%)	8(40% %)	2(10%)	
Embarrassed	43(100%)	23(53.5%)	20(46.5%)	14(70%)	6 (30%)	0	
Dribbling	43(100%)	23(53.5%)	20(46.5%)	11(55%)	8(40%)	1(5%)	
Cleaning braces bother you?	43(100%)	23(53.5%)	20(46.5%)	6(30%)	12(60%)	2(10%)	

Table 34 Patients' perception of treatment in relation to school work (Total sample)

Total study sample							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	43(100%)	23(53.5%)	20(46.5%)	4 (20%)	15(75%)	1(5%)	0
Eating	43(100%)	23(53.5%)	20(46.5%)	2(10%)	18(90%)	0	0
Drinking	43(100%)	23(53.5%)	20(46.5%)	3(15%)	17(85 %)	0	0
Sleeping	43(100%)	23(53.5%)	20(46.5%)	1 (5%)	18(90%)	1(5%)	0
Appearance	43(100%)	23(53.5%)	20(46.5%)	5(25%)	14(70%)	0	1(5%)
Teasing	43(100%)	23(53.5%)	20(46.5%)	1(5.2%)	18(90%)	0	1(5%)
	Number	Missing	Valid	Not at All	A little	A lot	
Sore teeth	43(100%)	24(55.8%)	19(44.2%)	14(73.7%)	5(26.3%)	0	
Sore mouth	43(100%)	24(55.8%)	19(44.2%)	14(77.7%)	5(26.3%)	0	
Sore rubbing	43(100%)	24(55.8%)	19(44.2%)	15(78.9%)	4(21.1%)	0	
Embarrassed	43(100%)	24(55.8%)	19(44.2%)	19(100%)	0	0	
Dribbling	43(100%)	24(55.8%)	19(44.2%)	18(94.7%)	1(5.3%)	0	
Cleaning braces bother you?	43(100%)	25(58.1%)	18(41.96%)	14(77.8%)	2(11.1%)	2(11.1%)	

Table 35 Patients' perception of treatment in relation to friendship (Total sample)

Total study sample							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	43(100%)	24(55.8%)	19(44.2%)	4 (21.1%)	15(78.9%)	0	0
Eating	43(100%)	25(58.1%)	18(41.9%)	2(11.1%)	16(88.9%)	0	0
Drinking	43(100%)	25(58.1%)	18(41.9%)	1(5.6%)	17(89.9 %)	0	0
Sleeping	43(100%)	24(55.8%)	19(44.2%)	1 (5.3%)	18(94.7 %)	0	0
Appearance	43(100%)	24(55.8%)	19(44.2%)	5(26.3%)	14(73.7%)	0	0
Teasing	43(100%)	24(55.8%)	19(44.2%)	1(5.3%)	18(94.7%)	0	0
	Number	Missing	Valid	Not at All	A little	A lot	
Sore teeth	43(100%)	24(55.8%)	19(44.2%)	18(94.7%)	1(5.3%)	0	
Sore mouth	43(100%)	24(55.8%)	19(44.2%)	17(89.5%)	2(10.5%)	0	
Sore rubbing	43(100%)	24(55.8%)	19(44.2%)	17(89.5%)	2(10.5%)	0	
Embarrassed	43(100%)	24(55.8%)	19(44.2%)	19(100%)	0	0	
Dribbling	43(100%)	24(55.8%)	19(44.2%)	18(94.7%)	1(5.3%)	0	
Cleaning braces bother you?	43(100%)	24(55.8%)	19(44.2%)	16(84.2%)	2(10.5%)	1(5.3%)	

Table 36 Patients' perception of treatment in relation to Family (Total sample)

Total study sample							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	43(100%)	24(55.8%)	19(44.2%)	1 (5.3%)	18(94.7%)	0	0
Eating	43(100%)	24(55.8%)	19(44.2%)	2(10.5%)	16(84.2%)	1(5.3%)	0
Drinking	43(100%)	24(55.8%)	19(44.2%)	2(10.5%)	17(89.5%)	0	0
Sleeping	43(100%)	24(55.8%)	19(44.2%)	0	18(94.7%)	1(5.3%)	0
Appearance	43(100%)	24(55.8%)	19(44.2%)	4(21.1%)	15(78.9%)	0	0
Teasing	43(100%)	24(55.8%)	19(44.2%)	2(10.5%)	16(89.5%)	0	0
	Number	Missing	Valid	Not at All	A little	A lot	
Sore teeth	43(100%)	24(55.8%)	19(44.2%)	16(84.2%)	3(15.8%)	0	
Sore mouth	43(100%)	24(55.8%)	19(44.2%)	17(89.5%)	2(1.5%)	0	
Sore rubbing	43(100%)	24(55.8%)	19(44.2%)	17(89.5%)	2(10.5%)	0	
Embarrassed	43(100%)	24(55.8%)	19(44.2%)	17(89.5%)	2(10.5%)	0	
Dribbling	43(100%)	24(55.8%)	19(44.2%)	18(94.7%)	1(5.3%)	0	
Cleaning braces bother you?	43(100%)	24(55.8%)	19(44.2%)	13(68.4%)	5(26.3%)	1(5.3%)	

Table 37 Tooth movement (Total sample)

Total study sample					
Do you feel that your teeth are moving?			Not at All	A little	A lot
Number = 43(100%)	**Missing=24(55.8%)**	**Valid= 19(44.2%)**	**1(5.3 %)**	**9(47.4%)**	**9(47.7%)**
Is it important for you whether or not your teeth are moving?			Not at All	A little	A lot
Number = 43(100%)	**Missing=24 (58.1)**	**Valid= 18(41.9%)**	**0**	**6(33.3%)**	**12(66.7%)**
Have you had extra visits because your brace was broken?			Yes	No	
Number = 43 (100%)	**Missing=24(55.8%)**	**Valid= 19(44.2%)**	**10(52.6%)**	**9(47.4%)**	
Did extra visit bother you?			Not at All	A little	A lot
Number = 43(100%)	**Missing=27(62.8)**	**Valid=16(37.2%)**	**12(70.6%)**	**5(329.4%)**	**0**
Is wearing a brace what you expected?			Yes	No	Not sure
Number = 43(100%)	**Missing=24(55.8%)**	**Valid= 19(44.2%)**	**12(66.7%)**	**3(16.7%)**	**3(16.7%)**
Overall experience with brace?			Positive	Negative	Neutral
Number = 43(100%)	**Missing=26(60%)**	**Valid=17(40%)**	**16(94%)**	**0**	**1(6%)**

Table 38 Treatment impact on hobbies (Total sample)

Total study sample					
Music			I enjoy	No different	I do less
Number = 43(100%)	Missing=27(62.8%)	Valid= 16(37.2%)	2 (12.5%)	14(87.5%)	0
Sport			I enjoy	No different	I do less
Number = 43(100%)	Missing=26(60.5%)	Valid= 17(39.5%)	3(17.6%)	12(70.6%)	2(11.8%)
Drama			I enjoy	No different	I do less
Number = 43(100%)	Missing=26(60.5%)	Valid= 17(39.5%)	5(29.4%)	12(70.6%)	0
Singing			I enjoy	No different	I do less
Number = 43(100%)	Missing=26(60.5%)	Valid= 17(39.5%)	3(17.6%)	12(70.6%)	2(11.8%)
Going to clubs eg Scouts or guides			I enjoy	No different	I do less
Number = 43(100%)	Missing=28(65.1%)	Valid= 15(34.9%)	2(13.3%)	12(80%)	1(6.7%)

Table 39 Patients' perception of treatment in general (Transpalatal arch)

Transpalatal arch							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	14(100%)	9(64.3%)	5(44.2%)	1 (20%)	4(80%)	0	0
Eating	14(100%)	9(64.3%)	5(44.2%)	1(20%)	3(60%)	1(20%)	0
Drinking	14(100%)	9(64.3%)	5(44.2%)	0	5(100%)	0	0
Sleeping	14(100%)	9(64.3%)	5(44.2%)	1(20%)	4(80%)	0	0
Appearance	14(100%)	9(64.3%)	5(44.2%)	4(80%)	1(20%)	0	0
Teasing	14(100%)	9(64.3%)	5(44.2%)	2(40%)	3(60%)	0	0
	Number	**Missing**	**Valid**	**Not at All**	**A little**	**A lot**	
Sore teeth	14(100%)	9(64.3%)	5(44.2%)	0	5(100%)	0	
Sore mouth	14(100%)	9(64.3%)	5(44.2%)	2(40%)	2(40%)	1(20%)	
Sore rubbing	14(100%)	9(64.3%)	5(44.2%)	3(60%)	2(40 %)	0	
Embarrassed	14(100%)	9(64.3%)	5(44.2%)	5(100%)	0	0	
Dribbling	14(100%)	9(64.3%)	5(44.2%)	3(60%)	1(20%)	1(20%)	
Cleaning braces bother you?	14(100%)	9(64.3%)	5(44.2%)	0	4(80%)	1(20%)	

Table 40 Patients' perception of treatment in relation to schoolwork (Transpalatal arch)

Transpalatal arch							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	14(100%)	9(64.3%)	5(44.2%)	1 (20%)	4(80%)	0	0
Eating	14(100%)	9(64.3%)	5(44.2%)	1 (20%)	4(80%)	0	0
Drinking	14(100%)	9(64.3%)	5(44.2%)	1 (20%)	4(80%)	0	0
Sleeping	14(100%)	9(64.3%)	5(44.2%)	1 (20%)	4(80%)	0	0
Appearance	14(100%)	9(64.3%)	5(44.2%)	2(40%)	3(60%)	0	0
Teasing	14(100%)	9(64.3%)	5(44.2%)	1(20%)	4(60%)	0	0
	Number	**Missing**	**Valid**	**Not at All**	**A little**	**A lot**	
Sore teeth	14(100%)	9(64.3%)	5(44.2%)	4(80%)	1(20%)	0	
Sore mouth	14(100%)	9(64.3%)	5(44.2%)	3(60%)	2(40%)	0	
Sore rubbing	14(100%)	9(64.3%)	5(44.2%)	2(40%)	3(60%)	0	
Embarrassed	14(100%)	9(64.3%)	5(44.2%)	5(100%)	0	0	
Dribbling	14(100%)	9(64.3%)	5(44.2%)	5(100%)	0	0	
Cleaning braces bother you?	14(100%)	9(64.3%)	5(44.2%)	4(80%)	1(20%)	0	

Table 41 Patients' perception of treatment in relation to friendship (Transpalatal arch)

Transpalatal arch							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	14(100%)	9(64.3%)	5(44.2%)	3(60%)	2(40%)	0	0
Eating	14(100%)	10(71.4%)	4(28.6%)	1(25%)	3(75%)	0	0
Drinking	14(100%)	9(64.3%)	5(44.2%)	1(20%)	4(80%)	0	0
Sleeping	14(100%)	9(64.3%)	5(44.2%)	1(20%)	4(80%)	0	0
Appearance	14(100%)	9(64.3%)	5(44.2%)	3(60%)	2(40%)	0	0
Teasing	14(100%)	9(64.3%)	5(44.2%)	1(20%)	4(80%)	0	0
	Number	**Missing**	**Valid**	**Not at All**	**A little**	**A lot**	
Sore teeth	14(100%)	9(64.3%)	5(44.2%)	5(100%)	0	0	
Sore mouth	14(100%)	9(64.3%)	5(44.2%)	5(100%)	0	0	
Sore rubbing	14(100%)	9(64.3%)	5(44.2%)	4(80%)	1(20%)	0	
Embarrassed	14(100%)	9(64.3%)	5(44.2%)	5(100%)	0	0	
Dribbling	14(100%)	9(64.3%)	5(44.2%)	5(100%)	0	0	
Cleaning braces bother you?	14(100%)	9(64.3%)	5(44.2%)	4(80%)	1(20%)	0	

Table 42 Patients' perception of treatment in relation to family (Transpalatal arch)

Transpalatal arch							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	14(100%)	9(64.3%)	5(44.2%)	1 (20%)	4(80%)	0	0
Eating	14(100%)	9(64.3%)	5(44.2%)	1(20%)	4(80%)	0	0
Drinking	14(100%)	9(64.3%)	5(44.2%)	1(20%)	4(80%)	0	0
Sleeping	14(100%)	9(64.3%)	5(44.2%)	0	4(80%)	1(20%)	0
Appearance	14(100%)	9(64.3%)	5(44.2%)	2(40%)	3(60%)	0	0
Teasing	14(100%)	9(64.3%)	5(44.2%)	1(20%)	4(80%)	0	0
	Number	**Missing**	**Valid**	**Not at All**	**A little**	**A lot**	
Sore teeth	14(100%)	9(64.3%)	5(44.2%)	3(60%)	2(40%)	0	
Sore mouth	14(100%)	9(64.3%)	5(44.2%)	4(80%)	1(20%)	0	
Sore rubbing	14(100%)	9(64.3%)	5(44.2%)	3(60 %)	2(40%)	0	
Embarrassed	14(100%)	9(64.3%)	5(44.2%)	5(100%)	0	0	
Dribbling	14(100%)	9(64.3%)	5(44.2%)	5(100%)	0	0	
Cleaning braces bother you?	14(100%)	9(64.3%)	5(44.2%)	4(80%)	1(20%)	0	

Table 43 Tooth Movement (Transpalatal arch)

Transpalatal arch					
Do you feel that your teeth are moving?			Not at All	A little	A lot
Number = 14(100%)	Missing=9(64.3%)	Valid= 5(35.7%)	1(20%)	0	4(80%)
Is it important for you whether or not your teeth are moving?			Not at All	A little	A lot
Number = 14(100%)	Missing=9(64.3%)	Valid= 5(35.7%)	0	0	5 (100 %)
Have you extra visits because your brace was broken?			Yes	No	
Number = 14(100%)	Missing=9(64.3%)	Valid= 5(35.7%)	4(80 %)	1(20%)	
Did extra visit bother you?			Not at All	A little	A lot
Number = 14(100%)	Missing=9(64.3%)	Valid= 5(35.7%)	4(80 %)	1(20%)	0
Is wearing a brace what you expected?			Yes	No	Not sure
Number = 14(100%)	Missing=9(64.3%)	Valid= 5(35.7%)	3(60%)	0	2(40%)
Overall experience with brace?			Positive	Negative	Neutral
Number = 14(100%)	Missing= 9 (64.3%)	Valid= 5(35.7%)	5(100%)	0	0

Table 44 Treatment impact on hobbies (Transpalatal arch)

Transpalatal arch					
Music			I enjoy	No different	I do less
Number = 14(100%)	Missing=9(64.3%)	Valid= 5(35.7%)	1(20%)	4(80%)	0
Sport			I enjoy	No different	I do less
Number = 14(100%)	Missing=9(64.3%)	Valid= 5(35.7%)	1(20%)	3(60%)	1(20%)
Drama			I enjoy	No different	I do less
Number = 14(100%)	Missing=9(64.3%)	Valid= 5(35.7%)	2(40%)	3(60%)	0
Singing			I enjoy	No different	I do less
Number = 14(100%)	Missing=9(64.3%)	Valid= 5(35.7%)	1(20%)	4(80%)	0
Going to clubs eg Scouts or guides			I enjoy	No different	I do less
Number = 14(100%)	Missing=10(71.4%)	Valid= 4(28.6%)	0	4(100%)	0

Table 45 Patients' perception on treatment in general (Miniscrews)

Miniscrews							
Patient's experience regarding	Number	Missing	Valid	Improved	Same	Slightly worse	Much worse
Speech	12(100%)	6 (50%)	6 (50%)	2 (33.3%)	3 (50%)	0	1 (16.7%)
Eating	12(100%)	6(50%)	6 (50%)	0	5 (83.3%)	1 (16.7%)	0
Drinking	12(100%)	6 (50%)	6 (50%)	2 (33.3%)	4 (66.7 %)	0	0
Sleeping	12(100%)	6 (50%)	6 (50%)	2 (33.3%)	4 (66.7%)	1 (16.7%)	0
Appearance	12(100%)	6(50%)	6(50%)	4(67.7%)	0	1 (16.7%)	1 (16.7%)
Teasing	12(100%)	7 (58.3%)	5 (41.7 %)	1(20%)	4 (80%)	0	0
	Number	Missing	Valid	Not at All	A little	A lot	
Sore teeth	12(100%)	6(50%)	6 (50%)	2(33.3%)	4(66.7%)	0	
Sore mouth	12(100%)	6(50%)	6(50%)	4 (66.7%)	2(33.3%)	0	
Sore rubbing	12(100%)	6(50%)	6 (50%)	5(83.3%)	1(16.7%)	0	
Embarrassed	12(100%)	6(50%)	6 (50%)	2(33.3%)	4(66.7%)	0	
Dribbling	12(100%)	6(50%)	6(50%)	2(33.3%)	4(66.7%)	0	
Cleaning braces bother you?	12(100%)	6(50%)	6(50%)	3(50%)	2(33.3%)	1(16.7%)	

Table 46 Patients' perception of treatment in relation to schoolwork (Miniscrews)

Miniscrews							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	12(100%)	6(50%)	6(50%)	3(50 %)	3(50%)	0	0
Eating	12(100%)	6(50%)	6(50%)	1(16.7%)	5(83.3%)	0	0
Drinking	12(100%)	6(50%)	6(50%)	2(33.3%)	4(66.7 %)	0	0
Sleeping	12(100%)	6(50%)	6(50%)	0	5(83.3%)	1(16.7%)	0
Appearance	12(100%)	6(50%)	6(50%)	2(33.3%)	3(50%)	0	1(16.7%)
Teasing	12(100%)	6(50%)	6(50%)	0	5(83.3%)	0	1(16.7%)
	Number	Missing	Valid	Not at All	A little	A lot	
Sore teeth	12(100%)	6(50%)	6(50%)	3(50%)	3(50%)	0	
Sore mouth	12(100%)	6(50%)	6(50%)	4(66.6%)	2(33.3%)	0	
Sore rubbing	12(100%)	6(50%)	6(50%)	6(100%)	0	0	
Embarrassed	12(100%)	6(50%)	6(50%)	6(100%)	0	0	
Dribbling	12(100%)	6(50%)	6(50%)	6(100%)	0	0	
Cleaning braces bother you?	12(100%)	7(58.3%)	5(41.6%)	3(60%)	1(20%)	1(20%)	

Table 47 Patients' perception of treatment in relation to friendship (Miniscrews)

Miniscrews							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	12(100%)	7(58.3%)	5(41.7%)	1(20%)	4(80%)	0	0
Eating	12(100%)	7(58.3%)	5(41.7%)	1(20%)	4(80%)	0	0
Drinking	12(100%)	8(66.7%)	4(33.3%)	0	4(100 %)	0	0
Sleeping	12(100%)	7(58.3%)	5(41.7%)	0	5(100%)	0	0
Appearance	12(100%)	7(58.3%)	5(41.7%)	1(20%)	4(80%)	0	0
Teasing	12(100%)	7(58.3%)	5(41.7%)	0	5(100%)	0	0
	Number	Missing	Valid	Not at All	A little	A lot	
Sore teeth	12(100%)	7(58.3%)	5(41.7%)	4(80%)	1(20%)	0	
Sore mouth	12(100%)	7(58.3%)	5(41.7%)	4(80%)	1(20%)	0	
Sore rubbing	12(100%)	7(58.3%)	5(41.7%)	5(100%)	0	0	
Embarrassed	12(100%)	7(58.3%)	5(41.7%)	5(100%)	0	0	
Dribbling	12(100%)	7(58.3%)	5(41.7%)	4(80%)	1(20%)	0	
Cleaning braces bother you?	12(100%)	7(58.3%)	5(41.7%)	4(80%)	1(20%)	0	

Table 48 Patients' perception of treatment in relation to family (Miniscrews)

Miniscrews							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	12(100%)	7(58.3%)	5(41.7%)	0	5(100%)	0	0
Eating	12(100%)	7(58.3%)	5(41.7%)	1(20%)	4(80%)	0	0
Drinking	12(100%)	7(58.3%)	5(41.7%)	1(20%)	4(80%)	0	0
Sleeping	12(100%)	7(58.3%)	5(41.7%)	0	5(100%)	0	0
Appearance	12(100%)	7(58.3%)	5(41.7%)	1(20%)	4(80%)	0	0
Teasing	12(100%)	7(58.3%)	5(41.7%)	1(20%)	4(80%)	0	0
	Number	**Missing**	**Valid**	**Not at All**	**A little**	**A lot**	
Sore teeth	12(100%)	7(58.3%)	5(41.7%)	4 (80%)	1(20%)	0	
Sore mouth	12(100%)	7(58.3%)	5(41.7%)	5(100%)	0	0	
Sore rubbing	12(100%)	7(58.3%)	5(41.7%)	5(100%)	0	0	
Embarrassed	12(100%)	7(58.3%)	5(41.7%)	4 (80%)	1(20%)	0	
Dribbling	12(100%)	7(58.3%)	5(41.7%)	4 (80%)	1(20%)	0	
Cleaning braces bother you?	12(100%)	7(58.3%)	5(41.7%)	3(60%)	2(40%)	0	

Table 49 Tooth movement (Miniscrews)

Miniscrews					
Do you feel that your teeth are moving?			Not at All	A little	A lot
Number = 12(100%)	Missing=7(58.3%)	Valid= 5(41.7%)	0	4(80%)	1(20%)
Is it important for you whether or not your teeth are moving?			Not at All	A little	A lot
Number = 12(100%)	Missing=8(66.7%)	Valid= 4(33.3%)	0	2(50%)	2(50%)
Have you extra visits because your brace was broken?			Yes	No	
Number = 12(100%)	Missing=7(58.3%)	Valid= 5(41.7%)	2(40%)	3(60%)	
Did extra visit bother you?			Not at All	A little	A lot
Number = 12(100%)	Missing=8(66.7%)	Valid= 4(33.3%)	3(75%)	1(25%)	
Is wearing a brace what you expected?			Yes	No	Not sure
Number = 12(100%)	Missing=7(58.3%)	Valid= 5(41.7%)	5(100%)	0	0
Overall experience with brace?			Positive	Negative	Neutral
Number = 12(100%)	Missing=8(66.7%)	Valid= 4(33.3%)	4(100%)	0	0

Table 50 Treatment impact on hobbies (Miniscrews)

Miniscrews					
Music			I enjoy	No different	I do less
Number = 12(100%)	Missing=7(58.3%)	Valid= 5(41.7%)	1(20%)	4(80%)	0
Sport			I enjoy	No different	I do less
Number = 12(100%)	Missing=7(58.3%)	Valid= 5(41.7%)	1(20%)	3(60%)	1(20%)
Drama			I enjoy	No different	I do less
Number = 12(100%)	Missing=7(58.3%)	Valid= 5(41.7%)	1(20%)	4(80%)	0
Singing			I enjoy	No different	I do less
Number = 12(100%)	Missing=7(58.3%)	Valid= 5(41.7%)	1(20%)	3(60%)	1(20%)
Going to clubs eg Scouts or guides			Missing=7(58.3%)	Valid= 5(41.7%)	I do less
Number = 12(100%)	Missing=7(58.3%)	Valid= 5(41.7%)	1(20%)	4(80%)	0

Table 51 Patients' perception on treatment in general (Headgear)

Headgear							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	17(100%)	8(47.1%)	9(52.9%)	1 (11.1%)	6(66.7%)	2(22.2%)	0
Eating	17(100%)	8(47.1%)	9(52.9%)	2(22.2%)	4(44.4%)	2(22.2%)	1(11.1%)
Drinking	17(100%)	8(47.1%)	9(52.9%)	0	9(100 %)	0	0
Sleeping	17(100%)	9(52.9%)	8(47.1%)	1(12.5%)	5(62.5%)	2(22.2%)	0
Appearance	17(100%)	8(47.1%)	9(52.9%)	4(44.4%)	3(33.3%)	2(22.2%)	0
Teasing	17(100%)	9(52.9%)	8(47.1%)	4(50%)	4(50%)	0	0
	Number	**Missing**	**Valid**	**Not at All**	**A little**	**A lot**	
Sore teeth	17(100%)	8(47.1%)	9(52.9%)	(33.3%)	6(66.7%)	0	
Sore mouth	17(100%)	9(52.9%)	8(47.1%)	0	8(100%)	0	
Sore rubbing	17(100%)	8(47.1%)	9(52.9%)	2(22.2 %)	5(55.6%)	2(22.2%)	
Embarrassed	17(100%)	8(47.1%)	9(52.9%)	7(77.8%)	2(22.2%)	0	
Dribbling	17(100%)	8(47.1%)	9(52.9%)	6(66.7%)	3(33.3%)	0	
Cleaning braces bother you?	17(100%)	8(47.1%)	9(52.9%)	3(33.3%)	6(66.7%)	0	

Table 52 Patients' perception of treatment in relation to schoolwork (Headgear)

Headgear							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	17(100%)	8(47.1%)	9(52.9%)	0	8(88.9%)	1(11.1%)	0
Eating	17(100%)	8(47.1%)	9(52.9%)	0	9(100 %)	0	0
Drinking	17(100%)	8(47.1%)	9(52.9%)	0	9(100 %)	0	0
Sleeping	17(100%)	9(52.9%)	8(47.1%)	0	9(100 %)	0	0
Appearance	17(100%)	8(47.1%)	9(52.9%)	1(11.1%)	8(88.9%)	0	0
Teasing	17(100%)	9(52.9%)	8(47.1%)	0	8(100 %)	0	0
	Number	**Missing**	**Valid**	**Not at All**	**A little**	**A lot**	
Sore teeth	17(100%)	9(52.9%)	8(47.1%)	7(87.5%)	1(12.5%)	0	
Sore mouth	17(100%)	9(52.9%)	8(47.1%)	7(87.5%)	1(12.5%)	0	
Sore rubbing	17(100%)	9(52.9%)	8(47.1%)	7(87.5%)	1(12.5%)	0	
Embarrassed	17(100%)	9(52.9%)	8(47.1%)	8(100%)	0	0	
Dribbling	17(100%)	9(52.9%)	8(47.1%)	7(87.5%)	1(12.5%)	0	
Cleaning braces bother you?	17(100%)	9(52.9%)	8(47.1%)	7(87.5%)	1(12.5%)	0	

Table 53 Patients' perception of treatment in relation to friendship (Headgear)

Headgear							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	17(100%)	8(47.1%)	9(52.9%)	0	9(100 %)	0	0
Eating	17(100%)	8(47.1%)	9(52.9%)	0	9(100 %)	0	0
Drinking	17(100%)	8(47.1%)	9(52.9%)	0	9(100 %)	0	0
Sleeping	17(100%)	10(58.8%)	7(41.2%)	0	9(100 %)	0	0
Appearance	17(100%)	8(47.1%)	9(52.9%)	1(11.1%)	8(88.9 %)	0	0
Teasing	17(100%)	10(58.8%)	7(41.2%)	0	8(100 %)	0	0
	Number	**Missing**	**Valid**	**Not at All**	**A little**	**A lot**	
Sore teeth	17(100%)	8(47.1%)	9(52.9%)	8(100%)	0	0	
Sore mouth	17(100%)	8(47.1%)	9(52.9%)	8(100%)	0	0	
Sore rubbing	17(100%)	8(47.1%)	9(52.9%)	8(100%)	0	0	
Embarrassed	17(100%)	8(47.1%)	9(52.9%)	8(100%)	0	0	
Dribbling	17(100%)	8(47.1%)	9(52.9%)	8(100%)	0	0	
Cleaning braces bother you?	17(100%)	8(47.1%)	9(52.9%)	8(100%)	0	0	

Table 54 Patients' perception of treatment in relation to family (Headgear)

Headgear							
Patient's experience regarding	**Number**	**Missing**	**Valid**	**Improved**	**Same**	**Slightly worse**	**Much worse**
Speech	17(100%)	8(47.1%)	9(52.9 %)	0	9(100 %)	0	0
Eating	17(100%)	8(47.1%)	9(52.9 %)	0	8(88.9 %)	1(11.1%)	0
Drinking	17(100%)	8(47.1%)	9(52.9 %)	0	9(100 %)	0	0
Sleeping	17(100%)	10(58.8 %)	7(41.2 %)	0	9(100 %)	0	0
Appearance	17(100%)	8(47.1%)	9(52.9 %)	1(11.1%)	(88.9 %)	0	0
Teasing	17(100%)	10(58.8 %)	7(41.2 %)	0	9(100 %)	0	0
	Number	**Missing**	**Valid**	**Not at All**	**A little**	**A lot**	
Sore teeth	17(100%)	8(47.1%)	9(52.9 %)	9(100%)	0	0	
Sore mouth	17(100%)	8(47.1%)	9(52.9 %)	1(11.1%)	(88.9 %)	0	
Sore rubbing	17(100%)	8(47.1%)	9(52.9 %)	9(100%)	0	0	
Embarrassed	17(100%)	8(47.1%)	9(52.9 %)	8(88.9%)	1(11.1%)	0	
Dribbling	17(100%)	8(47.1%)	9(52.9 %)	9(100%)	0	0	
Cleaning braces bother you?	17(100%)	8(47.1%)	9(52.9 %)	6(66.7%)	3(33.3%)	0	

Table 55 Tooth movement (Headgear)

Headgear					
Do you feel that your teeth are moving?			Not at All	A little	A lot
Number = 17(100%)	Missing=8(47.1%)	Valid=9(52.9%)	0	5(55.6%)	4(44.4%)
Is it important for you whether or not your teeth are moving?			Not at All	A little	A lot
Number = 17(100%)	Missing=8(47.1%)	Valid=9(52.9%)	0	4(44.4%)	5(55.6%)
Have you extra visits because your brace was broken?			Yes	No	
Number = 17(100%)	Missing=8(47.1%)	Valid=9(52.9%)	4(44.4%)	5(55.6%)	
Did extra visit bother you?			Not at All	A little	A lot
Number = 17(100%)	Missing=9(52.9%)	Valid=8(47.1%)	5(62.5%)	3(37.5%)	0
Is wearing a brace what you expected?			Yes	No	Not sure
Number = 17(100%)	Missing=8(47.1%)	Valid=9(52.9%)	4(44.4%)	4(44.4%)	1(11.1%)
Overall experience with brace?			Positive	Negative	Neutral
Number = 17(100%)	Missing=9(52.9%)	Valid=8(47.1%)	7(88.2%)	0	1(12.8%)

Table 56 Treatment impact on hobbies (Headgear)

Headgear					
Music			I enjoy	No different	I do less
Number = 17(100%)	Missing=11(64.7%)	Valid=6(35.3%)	0	6(100%)	0
Sport			I enjoy	No different	I do less
Number = 17(100%)	Missing=10(58.8%)	Valid=7(41.2%)	1(14.3%)	6(85.7%)	0
Drama			I enjoy	No different	I do less
Number = 17(100%)	Missing=10(58.8%)	Valid=7(41.2%)	2(28.6%)	5(71.4%)	0
Singing			I enjoy	No different	I do less
Number = 17(100%)	Missing=10(58.8%)	Valid=7(41.2%)	1(14.3%)	5(71.4%)	1(14.3%)
Going to clubs eg Scouts or guides			I enjoy	No different	I do less
Number = 17(100%)	Missing=11(64.7%)	Valid=6(35.3%)	1(16.7%)	4(66.7%)	1(16.7%)

Chapter 10. Discussion

10.1 Measurement of molar movement

The principal aim of this randomised clinical trial was to investigate the anchorage effectiveness of headgear, transpalatal arch and miniscrews. The findings from this trial showed that anchorage loss happened with all the three methods. In the headgear group, the mean anchorage loss for the left molar (1.85 mm) was greater than the mean anchorage loss in the transpalatal group (0.95mm) and the miniscrews group (0.87 mm). Interestingly, the mean anchorage loss for the right molar was greater in transpalatal group (1.23 mm) when compared with miniscrews group (0.39 mm) and headgear group (0.655 mm). This inconsistency in the results between the right and left sides could be attributed by the variation in sample size between the groups due to the large proportion of missing data in this trial and errors in the measurements. Nevertheless, the differences between the groups did not reach a statistically significant level. If the headgear would be the golden standard for anchorage reinforcement, it would reasonable to suggest that miniscrews and transpalatal arch are as effective as headgear in providing orthodontic anchorage. However the study is underpowered and should be interpreted with caution.

A similar study was undertaken by Sandler et al. (2014) but they used the Nance appliance instead of the transpalatal arch. The authors measured the anchorage loss of right and left molar in cephalometric radiographs as well as on 3D models. The measurements on 3D models used by Sander et al. (2014) was an identical method of measurements that had been used in this study. Similarly, they found that anchorage loss happened with all three treatment methods (Table 57), however, the differences between the groups were not statistically significant. Their findings suggested that miniscrews reinforced anchorage as effectively as headgear did. They suggested that miniscrews can be the recommended method of anchorage reinforcement when compared to headgear and Nance if the patients' satisfaction findings were combined with amount of anchorage loss. The findings of this trial are in agreement with Sandler et al. (2014). Although, Sandler et al. (2014) was a study with high standards, it could be criticised for using Nance appliance. The superimposition of the models was performed on the palatal rugae where the acrylic button of Nance appliance is resting. This might lead to inflammation of the palatal rugae which can cause errors during the superimposition process of the digital models.

Table 57 Means anchorage loss of the treatment groups found in Sandler et al (2014)

Molar movement	Miniscrews (n=22)	Nance (n= 26)	Headgear (n=23)
Upper left molar	0.99 (1.15)	2.09(1.32)	1.99(2.09)
Upper right molar	0.80 (1.60)	1.84(1.32)	1.36(1.83)

There are another 6 studies that investigated miniscrews in two-arm randomised clinical trials. Alsibaie and Hajeer (2014), Sharma et al. (2012), Basha et al. (2010), and Liu et al. (2009) compared miniscrews with transpalatal arch. While Upadhyay et al. (2008a) compared the miniscrews with variety of conventional methods. Ma et al. (2008) compared the miniscrews with headgear. All this six studies found significant difference in favour of miniscrews.

Alsibaie and Hajeer (2014) in a randomised clinical trial found that miniscrews not only prevented mesial movement of the upper molars, but also provided distal movement (-0.89 mm, SD= 0.59). They found that this amount of distal molar movement in the miniscrews group was significantly different from the mesial molar movement (1.5mm, SD= 1.25) in the transpalatal arch group. The authors performed their measurements on lateral cephalometrics. These findings about miniscrews were not in agreement with our findings.

Sharma et al (2012) observed no changes in the upper molars in the miniscrews group (0.0, SD= 0.02) and 2.48 mm (SD= 0.71) of mesial movement of the upper molars in the transpalatal arch group. The difference between the two groups was statistically significant. The authors measured the molar movement on lateral cephalometrics rather than using 3D models. Also, they did not measure the molars movement of the right side and left side separately.

Findings from Basha et al. (2010) were similar to Sharma et al. (2012). They observed no changes in the miniscrews group and 1.73mm (SD= 0.43) of mesial movement of the molar when the transpalatal arch was used. They reported that the difference was statistically significant between the two groups without mentioning the P value of student t test. Moreover, the authors recruited seven patients in each

group which may have made the study underpowered. They also derived their findings from measurements on lateral cephalometrics.

In Liu et al. (2009) randomised clinical trial, the miniscrews provided a small amount of molar distalisation in the miniscrews group (0.06mm, SD 1.4) while the direction of upper molar movement was mesial (1.47 mm, SD 1.15) in the transpalatal arch group. The changes between the two groups reached significant difference. Again, the authors used lateral cephalometrics to quantify the molar movement in the two treatment group. Interestingly, the authors mentioned that the amount of molar distalisation in the miniscrews group was modest when compared with a previous study that they carried out despite continuing the retraction force after space had been closed in both studies. They mentioned that they recruited patients aged 14-33 in that previous study while they included patients older than 18 years old in this recent study. They suggested that the molar region was stronger in adult patients and therefore only modest molar distalisation was achieved in the recent study. However, Alsibaie and Hajeer (2014) recruited patients with average age of 22.34 years (SD 4.6) and yet achieved o.89 mm (SD 0.59) of molar distalisation in the miniscrews group.

Upadhyay et al. (2008a) carried out a randomised clinical trials and reported 0.78 mm of molar distalisation movement when miniscrews were used. Similarly to Alsibaie and Hajeer (2014) and Basha et al. (2010), some molar distalisation was noted in the miniscrews group in Upadhyay et al (2008). The second arm of their trial was conventional anchorage method Including headgear, transpalatal arch, banding second molar, and application of differential moments which had mesial movement of the upper molars of 3.22 mm. The difference between the two groups was statistically significant. Like previous studies, the authors used cephlometric as the source of their findings and did perform separate measurements of the right and left molars.

Unlike the previous five two-arm trial, Ma et al. (2008) compared the effectiveness of miniscrews in anchorage reinforcement to a headgear group. The authors did not provide a clear description of the linear measurements of their findings including the amount of molar movement. Alternatively, they reported the angular changes to teeth that resulted of using miniscrews or headgear as part of the treatment. They

found that maxillary incisors were moved palatally in both groups without significant anchorage loss but the amount of retraction was more in the miniscrews than the headgear which reached statistical level. Again, lateral cephalometrics were the source of their findings.

The conclusion of the previous six trials (Alsibaie and Hajeer 2014; Sharma et al., 2012; Basha et al., 2010; Liu et al., 2009; Upadhyay et al., 2008a; Ma et al. , 2008) differed from the findings of this trial. The authors of the previous studies reported a statistically significant difference for miniscrews over transpalatal arch and headgear in providing anchorage reinforcement. These different conclusions could justified by different design in our three-arm trial in which patients were randomised to three treatment groups rather than two groups. Also, the data for this trial was collected from six centres while the previous trials were conducted in single centre except for Upadhyay et al. (2008a) whose the trial was conducted in two centres.

Furthermore, the authors of the previous six trials derived their findings from measurements on lateral cephalometrics which have questionable accuracy. Besides, the authors did not perform individual measurements on the right and left molars. Instead, they identified the average position of right and left molar which increased the degree of inaccuracy of their measurements. In this trial, the movement of right and left molars were measured more accurately using 3D models.

Additionally, the amount of missing data underpowered this study and it may have led to different conclusion from the previous six studies. However, the findings of Sandler et al. (2014) high standard three-arm trial were in agreement with this study. Similar to this trial, they have used 3D measurements to quantify the amount of molar movement which suggested that the findings of this study would be more close to the real effect of treatment.

10.2 Patients' views of the treatment

The patients' views on the treatment were measured through "before treatment" and "after treatment" questionnaire. Not all records had been retrieved from the patients and this was reflected on the small number size of analysed data. The power of the statistical tests comparing the groups to each other were therefore underpowered. It

may be inaccurate to draw any conclusion from this statistical testing. However, the descriptive statistics of patients' answers were presented in Tables 26-32. Also, comparison with other clinical trials in relation to patients' views before and after the treatment was not possible as they did not report any data regarding this topic.

10.3 Patients' perception of the treatment.

The patients' perception of the treatment were measured through "smile better" questionnaire. It gathered information on the patient' perception of the treatment effect on speaking, eating, drinking, appearances and hobbies and interests. The questionnaire was originally developed by O'Brien et al. (2003) to investigate patients' perception to functional appliances. It was expected that patients' experience to fixed appliances would be different from functional appliance. However, it was felt that the questionnaire could be still used with adolescent patients who receive orthodontic treatment in this trial. Nonetheless, it would not be informative to make statistical comparison between the three groups due to the small number of the collected data. Descriptive statistics were presented in Tables 33-56.

Sandler et al. (2014) was the only other trial that measured the patients' perception of the treatment. The patients in Nance and miniscrews groups in Sandler et al. (2014) trial completed a questionnaire about comfort and discomfort levels of placement and removal of both Nance and miniscrews. The patients in the headgear group completed a different questionnaire about their clinical experience with the headgear. From information gathered from the free text section and level of discomfort questionnaire, the authors found no significant difference in patients' acceptance to miniscrews or Nance. In contrast, the headgear patients' responses had reflected that they preferred not to have headgear as a part of their treatment. The authors suggested that patients' experience in general was more positive towards miniscrews in comparison to headgear.

10.4 The power of the study

The results should be interpreted with caution given that the study had insufficient power leaving it prone to type two errors where the false null hypothesis not rejected. However, there was agreement with the findings of previous studies that

miniscrews can be used as alternative to headgear in order to reinforce anchorage during orthodontic treatment.

Poor recruitment in clinical trials reduces their power and generalisability. The reasons for poor recruitment are multi-factorial. Cunningham et al. (2011) highlighted some reasons for a slow rate recruitment through discussion of two orthodontic clinical studies. Their first study aimed to compare two different methods of treatment in orthodontic patients, while the second aimed to investigate the association between tempromandibular joint (TMJ) status and the type of malocclusion on patients or volunteers. Research teams in both studies decided to terminate the studies early due to difficulties in achieving the target number of participants. Cunningham and her colleagues argued that recruitment difficulties in orthodontics studies may occur due to difficulties in obtaining consent from parents/guardians for paediatric trials, orthodontic treatment can take a significant numbers of years to complete; and different orthodontists prefer using different treatment planning and mechanics.

Additionally, the nature of orthodontic clinical trials does not facilitate blinding of interventions. Therefore the patients would be able to differentiate between the treatments and may have a preference of one treatment over the other. Thus, the advantage of random allocation concept in clinical trial design may not be clear to them. This is applicable to this clinical trial especially as the treatment arms mode of action differed greatly from each other. Local anaesthesia was required for miniscrews, laboratory work was required for transpalatal arch and headgear demanded Patient Corporation and compliance for 12-14 hours a day. Sandler et al. (2014) found that 10 of 23 patients allocated to a headgear group held negative views about headgear. Interestingly, this might be shared by some orthodontists as some studies have found a decline in the trend of headgear use. Tüfekçi et al. (2015) surveyed 1000 orthodontists in North America and out of the 948 who responded, 38% reported that they were not using headgear. The chance to be allocated to headgear may have caused the patients to decline participation in the trial. However, it was emphasised on the investigators of the trial to consider the headgear as the gold standard and hence the default method of anchorage reinforcement. Nevertheless, that did not appear to help in recruiting more participants in to the trial.

Ambiguous understanding of the concept of equipoise in a clinical trial during the recruitment stage may have been a factor in slow recruitment rate. Equipoise in clinical trials is the concept in which the knowledge available from evidence about advantages and disadvantages of a trial's interventions is equal (Freedman, 1987). Freedman suggested that global clinical equipoise should be favoured even in the case of the clinician's absence of equipoise. The individual investigator should invite patients to participate into a study even if their personal view favours a type treatment over another. It is the duty of the ethics committee to ensure the treatments that are being compared are reasonable before the trial commences (Parsons et al., 2011).

Strategies to improve participants' recruitment in randomised clinical trials were investigated by a Cochrane review performed by Treweek et al. (2010). They found that methods including telephone reminders, use of opt-out procedure where participants need to contact the research team if they do not wish to participant in the trial, and open design instead of blind trial to be effective in improving participants' recruitment in randomised clinical trials. However, all these methods were not applicable to this trial because of the nature of orthodontic treatment where treatment cost is covered by NHS. Thus, contacting patients would not be necessary as they would be seen by a clinician in order to receive the treatment regardless of their participation in the trial. Open trial design was not applicable as neither the clinician nor patient could be blinded to treatment allocation.

Achieving target recruitment rate has been a challenge for researchers conducting clinical trials. McDonald et al found that in 53% of the trials they investigated the recruitment time needed to be modified (McDonald et al., 2006). The most common reported reason was that the investigators observed less than expected eligible participants. McDonald and her colleagues reported that only one third of the trials recruited 100% of the projected number, while 45% targeted less than 80% of their projected target.

Low recruitment rate is a complex and challenging problem in health research. This trial is one of these trials in which the research team faced difficulty to recruit enough patients in order to meet the projected target. That resulted in extending the

planned time for the trial. Despite this shortcoming, the trial has still provided valuable information and lesson about the nature of clinical trials for future orthodontic researchers. It is important for orthodontists to investigate the nature of clinical trials and develop strategies that improve patients' recruitment in orthodontics in particular.

Another reason that may have caused the insufficient power in this study is the missing data. This trial was a multi-centre trial and involved nine sites in a wide geographical area. Also, the recruitment phase started in 2008. Due to the prolonged duration, the trial management was challenging. Some of these challenges were meeting the target sample size, insurance of the compliance to trial protocol across all sites, monitoring data collection processes and avoidance of missing the data. Unfortunately, 51% study models which were supposed to be taken at the middle of the treatment to allow for anchorage loss measurements of upper molars were not taken. Similarly, the questionnaires about patients' views of the treatment and their perception were not collected. 42% and 65% of the data were missing from "before treatment" and "after treatment" questionnaires respectively. 53% of the data were missing for "smile better" questionnaire that were meant to be collected in the middle of the treatment.

The trial was extended twice to enhance the recruitment of participants. This may have resulted in the data becoming not retrievable for some sites because patients were recruited early in the trial and their data got misplaced over time. Also, the nature of outcome variable required the active participation of patients in alginate impression taking and filling in questionnaires which may have contributed to the number of missing data. Necessity of extra procedures to collect data in the routine treatment visit which the investigators may not have thought of because of the clinical time pressure may have been challenging to the investigator. Except from Sandler et al. (2014), all the previous trials derived their findings from lateral cephalometrics which are taken routinely before treatment commences and in the middle of the treatment. Whereas in this trial, alginate impression was required after the bands had been removed for mid-treatment study model fabrication.

Additionally, only Sandler et al. (2014) collected secondary outcomes through questionnaires answers. Moreover, all the previous trials were conducted in single

centre with the exception of Sandler et al. (2014) and Upadhyay et al. (2008a) that were conducted in two centres only which may have enhanced the controllability over the trial management process.

Sites were visited several times by the author and trial manager to insure that the study protocol was followed to collect data. Likewise, several issues of newsletters (Appendix 11) were distributed and email correspondence was carried out with principal investigators to enhance the adherence to the study protocol. Unfortunately, data were still missing. The investigators in the trial had a good track record with respect to recruiting and following patients and collecting necessary information in previous clinical trials. Still, difficulties in recruitment arose and it was decided to extend the recruitment phase. Also, more researchers were added to the trial panel in order to extend the burden of the trial and enhance the participant recruitment. The projected recruitment target was finally achieved. Unfortunately, the missing data problem arose afterwards. This may have happened as a trade-off to the extended time scale of the trial as well as due to adding more junior researchers where missing data is more likely to happen.

Lessons from this trial can help as a guidance for e researchers interested in performing clinical trials in future. The input of a research nurse available in each trial site to insure the data collected in required time points according to the protocol could have been helpful. Also, data collection reminder alerts could be provided to remind the investigators to collect the data would be helpful in respect to data collection. Furthermore, questionnaires could be filled electronically on a website designed for the trial. Also, the website could foster communication between patients and management board and enhance their engagement with the trial.

In summary, there is no easy solution for slow recruitment rate and missing data issues in clinical trials. It is important for researchers to carefully design and conduct clinical trials in a way that would minimise the probabilities of these shortcoming from happening in the first place.

Conclusion

This randomised clinical trial revealed that there is no difference in relation to anchorage effectiveness between miniscrews, transpalatal arch and headgear. However, the findings of this trial should be interpreted with caution due to the considerable amount of missing data.

Chapter 11. Overall conclusions.

Miniscrews have become popular in contemporary orthodontic practice. This thesis details research that investigates miniscrews' effectiveness in orthodontics. Each of the studies that fed into this Thesis added to the current evidence about miniscrews. In addition, it added to our understanding about the quality of conducted randomised clinical trials in orthodontics and their reporting.

On the basis of the research findings, the following conclusion can be made:

- The systematic review and meta-analysis of miniscrews failure rate showed that miniscrews have a modest failure rate and they are useful clinically to reinforce anchorage.
- The current usage of miniscrews in the UK did not meet the standards. Inflammation/ infection around screws resulting in loss or removal was the only item met the standards.
- The project about the quality of reporting clinical trials in orthodontics revealed that clinical trial reports represented less than 5% of articles and their reporting is still suboptimal.
- The conducted clinical trial support the null hypotheses that there is no difference in treatment process, treatment outcome, or patients' experience between using AbsoAnchor miniscrews , transpalatal arch or Headgear to reinforce anchorage. Miniscrews can be used as alternative anchorage method to headgear and transpalatal arch in order to reinforce anchorage in orthodontics.

Recommendations for future work:

- Continue miniscrews national audit with annual reports to allow operators to make ongoing comparison with the national data.
- An update on the quality of reporting clinical trials in orthodontics project: 2012-2017.
- A RCT investigating direct versus indirect orthodontic anchorage using miniscrews.

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Appendices

Appendix 1. Copies of published/accepted papers based on this project

CLINICAL SECTION

Journal of Orthodontics, Vol. 42, 2015, 214–219

British Orthodontic Society national audit of temporary anchorage devices (TADs): report of the first thousand TADs placed

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Objective: To provide data from the British Orthodontic Society (BOS) national clinical audit on temporary anchorage device (TAD) use following the recommendations of the National Institute for Health and Clinical Excellence (NIHCE) **Design and setting:** The Audit commenced on 1 January 2008 and is still ongoing. This article reports the data for TADs placed from 1 January 2008 to 1 November 2013. **Materials and methods:** Audit data was collected from participants using a system of both on-line data entry and hard copy forms. The criteria and standards for the audit were set following the NIHCE report in conjunction with the Development and Standards Committee of the BOS. Virtually all participants used the on-line data entry available on the BOS website. The data submitted was checked and entered manually into an Excel spreadsheet, and transferred to SPSS for analysis. **Results:** Written information and documented discussion of risks were provided in over 90% of TADs placed, but 17.4% were placed without a specific signed consent form. Temporary anchorage device failure rate was 24.2% overall. Among failed TADs, 93.1% were lost or removed due to excess mobility. Infection or inflammation resulting in loss or removal was reported in 6% of TADs. **Conclusions:** The only audit standard that was met was failures due to infection of inflammation. The rest of the audit standards were not met. Recommendations are made to address these issues.

Key words: Clinical audit, temporary anchorage device, orthodontics, British Orthodontic Society

Received 15 June 2014; accepted 17 April 2015

Introduction

Successful anchorage management is an important factor in achieving optimal treatment outcome in orthodontics. Orthodontists have conventionally used extra oral appliances, such as headgear to provide additional anchorage when required, although this can still be associated with anchorage loss, as it is highly dependent on patient compliance (Brandao *et al.*, 2006; Dalessandri *et al.*, 2014). Recently, anchorage has been described as being obtainable without relying on patient compliance through use of temporary anchorage devices (TADs). Temporary anchorage devices include non-osseointegrated miniscrews, which are inserted into alveolar bone to provide anchorage during orthodontic treatment and removed when no longer required (Tsui *et al.*, 2012; Dalessandri *et al.*, 2014). Miniscrews have the advantages of being small in size, simple to place and remove, relatively inexpensive, not requiring laboratory work and being able to be immediately loaded; all of which, makes them a convenient option for providing anchorage in different anatomical sites.

Schatzle *et al.* (2009) in their systematic review described a failure rate of 16.4% among 2374 TADs placed in 1196 patients from 17 studies. In a recent systematic review, including meta analysis of 4987 TADs placed in 2281 patients from 52 studies, TAD failure rate was estimated to be 13.5% with failure rate in the mandible higher than in the maxilla. The authors attributed the higher failure rate in the mandible in comparison to maxilla to differences in bone density, bone overheating during insertion, the varibility of cortical bone availibity around the TAD and the fact that the mandible has a narrower vestibule (Papageorgiou *et al.*, 2012).

Clinical audit is a key mechanism for quality improvement of services provided to patients (Bullivant and Corbett-Nolan, 2010). The National Institute for Health and Clinical Excellence (NIHCE), a component of the UK National Health Service concerned with raising the standards of health and social services by providing recommendations, guidance and standards to care providers, reported on the use of TADs and provided

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Table 1 Audit standards and results

	Data recorded	Standard	Yes	No	Standard met
Baseline data					
Was written information on procedure given to patient?	Y/N	100%	91.7% (983/1072)	8.3% (89/1072)	No
Documented discussion re procedure & risks	Y/N	100%	90% (965/1072)	10% (107/1072)	No
Signed consent form present	Y/N	100%	82.6% (885/1072)	17.4% (187/1072)	No
Point of insertion	Maxilla/mandible Buccal/lingual		80.8% (866/1072)/19.2% (206/1072) 86.4% (926/1072)/13.6% (146/1072)		
Was local anaesthesia used?	Y/N		98.9% (1060/1072)	1.1% (12/1072)	
Was a flap raised/incision made?	Y/N		8.1% (87/1072)	91.9% (984/1072)	
Was drilling with a pilot drill* performed?	Y/N		4.3% (46/1072)	95.7% (1026/1072)	
Was drilling with a bur** performed?	Y/N		10.5% (113/1072)	89.5% (959/1072)	
Was a stent used to aid placement?	Y/N		12.4% (133/1072)	87.6% (939/1072)	
Was the TAD loaded immediately?	Y/N		79% (847/1072)	21% (225/1072)	
Follow-up data					
Failure?	Y/N	<20%	Failure 24.2% (259/1072)	Removal 75.8% (813/1072)	No
Screw replaced following loss or removal?	Y/N		9% (97/1072)	91% (975/1072)	
Screw lost or removed before completion of anchorage period?	Y/N	<20%	22.1% (237/1072)	77.9% (835/1072)	No
Anchorage required provided by screw without adverse effects?	Y/N	70%	67.6% (725/1072)	32.4% (347/1072)	No
Reasons of failure (more than one reason for failure in some TADs)					
Infection	Y/N	<20%	0.6% (6/1072)	99.4% (1066/1072)	Yes
Inflammation	Y/N	<20%	5% (54/1072)	95% (1018/1072)	Yes
Mobility	Y/N		22.5% (241/1072)	77.5% (831/1072)	
Adverse effects					
Inflammation/infection reported as adverse effects	Y/N/N		9.7% (105/1072)	90.2% (967/1072)	
Mobility reported as adverse effects	Y/N		18.9% (203/1072)	81.1% (869/1072)	
Damage to neighbouring teeth reported as adverse effects	Y/N	0%	0.7% (7/1072)	99.3% (1065/1072)	No

*The use of a punch or bur to make a soft tissue puncture.
**The use of a drill to prepare a hole to the full depth of the TAD.

Discussion

The most frequent piece of missing information in the clinical documentation was a consent form specifically recording TADs as part of treatment. This could have been due to an understanding of some participants that the overall orthodontic treatment consent is sufficient, without the need for a separate consent form or specific entry for TADs. However, NIHCE guidance recommends providing a specific consent form when placing a TAD.

A total of 53.2% of TADs were placed in the upper buccal segment, either between the upper first and second molar or more frequently, between upper second premolar and upper first molar. This would seem to

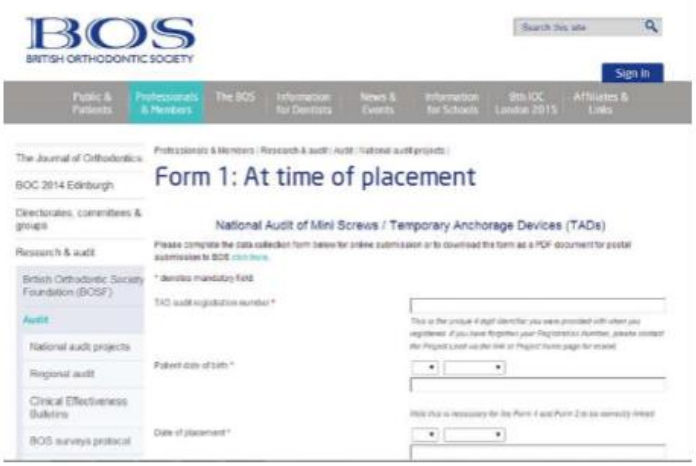

Figure 1 Online data entry form

indicate that the most common uses of TADs are for incisor or canine retraction, molar distalisation or buccal segment intrusion.

In this audit, the national failure rate (24.2%) is greater than the failure rate reported previously in systematic reviews [13.5% (Papageorgiou *et al.*, 2012)

BOS National Audit of mini screws / temporary anchorage devices (TADs)

DATA COLLECTION SHEET 1: AT TIME OF MINI-SCREW / TAD PLACEMENT

TAD Audit Registration Number			Patient Date of Birth (if known)		/ /
Date of placement (if known)		/ /	Unique patient identifier i.e. hospital / practice number		
Was written information on procedure given to patient?		Yes / No	Is there documented evidence of discussion re procedure & risks?		Yes / No
Signed consent form in patient record?		Yes / No	Number of mini-screws / TADs inserted (if more than 4 complete box audit sheets)		

		TAD #1	TAD #2	TAD #3	TAD #4
Make of TAD (e.g. Infinitec / Vector etc)					
Length of screw					
Diameter of screw					
TAD location	Which jaw?	Max / Mand	Max / Mand	Max / Mand	Max / Mand
	Lingual or Labial?	Lingual / Labial	Lingual / Labial	Lingual / Labial	Lingual / Labial
	Adjacent teeth (OS inclusion)				
Was local anaesthetic infiltration used?		Yes / No	Yes / No	Yes / No	Yes / No
Was a flap raised / incision made?		Yes / No	Yes / No	Yes / No	Yes / No
Was drilling with a pilot drill performed?		Yes / No	Yes / No	Yes / No	Yes / No
Was drilling with a bur performed?		Yes / No	Yes / No	Yes / No	Yes / No
Was a stent or guide used?		Yes / No	Yes / No	Yes / No	Yes / No
Was mini-screw / TAD loaded immediately?		Yes / No	Yes / No	Yes / No	Yes / No
Additional comment on placement					

Delete responses as appropriate

When sheet completed send to TAD Audit, BOS, 12 Bridewell Place, London EC4V 6AP

Figure 2 Hard copy data entry form

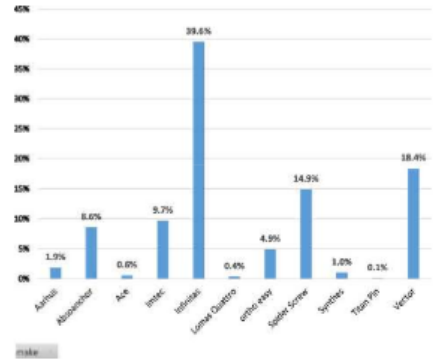

Figure 3 Distribution of TADs according to system

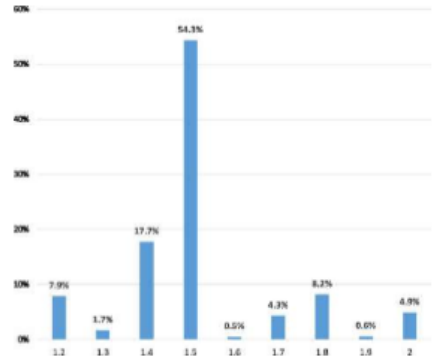

Figure 5 Distribution of TADs according to diameter

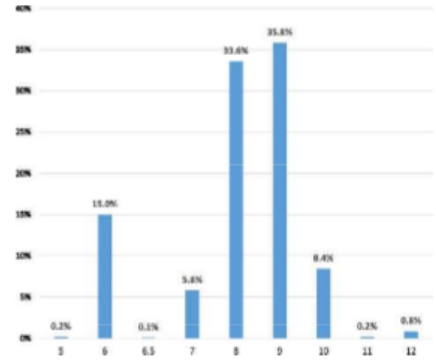

Figure 4 Distribution of TADs according to length

and 16.4% (Schatzle *et al.*, 2009)] but within the range reported in local audits, including 20% (Mistry and Cousley, 2009), 10% (Cousley, 2011) and 47% (Barber and Morris, 2003). This difference in failure rate could be explained by the fact that data presented here were collected from 71 different sites, where the participants have variable experience in using TADs, whereas in other reports data usually represent the practice of a few experienced operators. This is supported by the finding that low volume operators had a higher failure rate, and in this study the high volume operators had a failure rate closer to that in previously published studies. Following detailed protocols in research studies may also contribute to the higher success rate of TADs in these studies, while audit data is more likely to reflect the real world current practice.

Failure rate was significantly higher in the mandible (31.1%) than in the maxilla (22.5%), which agrees with other studies (Cheng *et al.*, 2004; Park *et al.*, 2006; Chen *et al.*, 2006; Papageorgiou *et al.*, 2012). This difference in success rate may explain the greater popularity of using TADs in the maxilla (866 TADs) compared to mandible (206 TADs) as well as the differences in clinical use where placing TADs in the mandible is often more difficult.

Temporary anchorage devices, which did not fail, on average were in place for 349.7 days. Schatzle *et al.* (2009) in their systematic review found that average loading time ranged from 120 days to more than 1 year, which is consistent with the findings in this study. Of the TADs that failed, 44.3% had failed or were removed in the first 2 months after initial placement, most frequently due to excess mobility. This would indicate that if a TAD is going to fail, it is most likely to do so soon after insertion.

Data collection for this self-reporting project depended on participants' subjective judgement. To limit the effects of this subjectivity, clear explanations of the data entry choices were embedded as notes in the online form. Another limitation of this project is that although this audit was designed to cover all types of temporary anchorage devices, all collected data related to miniscrews. This could be due to orthodontist's preference for using miniscrews over other types of TADs, such as onplants or mini-plates. Some two-thirds of participants in this audit were based in secondary care in a hospital setting. This does not reflect the overall balance of BOS membership, and may therefore reflect the greater opportunity for hospital-based practitioners to

participate in audit, or may indicate that TAD usage is greater in this sector.

The audit standards were set in 2007 and advances in TAD design and clinical applications since then would suggest that the TAD Audit standards currently recommended should be revised in the light of published data, to provide a more realistic expectation of how TADs should be expected to perform in current clinical practice.

Conclusion and recommendations

This report of the BOS TAD audit data from 1 January 2008 to 1 November 2013 shows that nationally, the following audit standards are being achieved:

> Infection/inflammation around the screw resulting in loss or removal in 5.6% of the cases met the standards of being below 20%.

However, the following audit standards are not being achieved:

> written information on procedure was given to the patient in 91.7% of cases, while the standard is 100%;
> documented discussion regarding procedure and risks was available in 90% of cases, while the standard is 100%;
> a signed consent form was present in the patient record in 82.6% of cases, while the standard is 100%;
> anchorage was provided without adverse effects in 67.6% of cases, while the standard is greater than 70%;
> screws lost or removed before completion of the anchorage period occurred in 24.2% of cases, while the standard is less than 20%; and
> damage to neighbouring teeth occurred in 0.7% of cases, where the standard is 0%.

We would make the following recommendations for clinical audit and clinical practice:

> audit standards should be reviewed in the light of new data and clinical practice as TADs become increasingly a part of routine clinical practice. This should include reviewing the requirement for separate recording of consent;
> operators or units with failure rates higher than the national average of 24% should review their clinical procedures;
> low volume operators or units should in particular, monitor failure rates as these are likely to be greater than the national average and
> national audit with annual reports should continue to allow individual operators and units to make ongoing comparisons with national data.

Disclaimer Statements

Contributors Prof David Bearn developed the project from initial concept and was jointly responsible for data analysis, critical revision and approved the manuscript and is the guarantor. Dr Fahad Alharbi was responsible for data collection and drafting the manuscript, and jointly responsible for data analysis.

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Ethics approval This audit project was approved by the BOS Standards and Development Committee. As an audit project ethical approval was not required or sought.

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Reporting of clinical trials in the orthodontic literature from 2008 to 2012: observational study of published reports in four major journals

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Objective: The aim of this study is to provide an update as to whether authors in the orthodontic field of research currently report randomized clinical trials (RCTs) adequately as defined by the Consolidated Standards of Reporting Trials (CONSORT) statement. **Methods:** The American Journal of Orthodontics and Dentofacial Orthopedics (AJO-DO), Journal of Orthodontics (JO), European Journal of Orthodontics (EJO) and Angle Orthodontist (AO) were reviewed to identify all articles that reported RCTs published between January 2008 and June 2012.Reports were scored using the CONSORT 37 item checklist. A 10% random sample of the papers was scored by a second examiner to assess inter-examiner reliability of the CONSORT score. Another 10% random sample of the papers was scored a second time by the first examiner 3 months after initial data collection to test intra-examiner reliability. **Results:** A total of 151 clinical trial reports have been identified out of 3335 articles in the four journals from January 2008 to June 2012.Mean CONSORT score of the four journals was 51.7%. Journal of Orthodontics achieved the highest score of 73.6% and the lowest score was achieved by AO with a score of 44.5%. Overall compliance with CONSORT increased from 47.8 to 56.3% between 2008 and 2012. **Conclusion:** Clinical trials reports represented <5% of articles in the four main orthodontic journals between 2008 and 2012.

- CONSORT mean score ranged from 44.5 to 73.6% between journals.
- CONSORT mean score increased through the period of investigation.

Key words: CONSORT statement, clinical trial, standards, reporting, orthodontic research

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Introduction

Well conducted and reported randomized clinical trials (RCTs) are considered the foundation for evidence-based dentistry today. Poorly conducted RCTs can lead to either an overestimation or an underestimation of the effect of the tested treatment. To be able to assess the quality of an RCT accurately, readers of a published report need complete, clear and transparent information on its methodology, analysis and findings (Schulz *et al.*, 2010). Unfortunately, many trial reports fail to provide clear and complete descriptions, making it difficult to assess the study quality.

The lack of adequate reporting fuelled the development of the original Consolidated Standards of Reporting Trials (CONSORT) statement in 1996 (Begg *et al.*, 1996), its revision 5 years later (Moher *et al.*, 2001) and further updates in 2010 (Schulz *et al.*, 2010). CONSORT group members have presented a 37-point checklist of information to include when reporting an RCT. The CONSORT statement has been endorsed by over 400 different journals to date, representing over 50% of the core medical journals listed in the *Abridged Index Medicus* on PubMed (CONSORT Statement, 2011)

Studies in different medical disciplines have looked at research quality and reporting quality in medical research. Several investigations in the medical literature have found that the quality of reporting is inadequate. The quality of reporting RCTs in five leading general medical journals has been evaluated and found to be inadequate (Mills *et al.*, 2005). Two systematic reviews (Plint *et al.*, 2006; Falagas *et al.*, 2009) of studies evaluating the quality of RCT reporting in different medical specialities and a Cochrane review (Turner *et al.*, 2012) have been published. Both systematic reviews found that although endorsement of CONSORT statement by journals improve RCT reporting, authors still report their trials inadequately. In dentistry, the quality of RCT reporting in dental speciality journals with the highest impact factor was investigated, with the quality of reporting suboptimal – with a 62% mean

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score for completeness of reporting with regard to the CONSORT statement check list (Pandis *et al.*, 2010).

Harrison assessed 155 trials published in three orthodontic journals between 1989 and 1998, using the Jadad scale for the assessment of the quality of RCTs. She found that 137 trials had a high risk of bias, 17 trials had moderate risk of bias and only one trial had low risk of bias. She also concluded that in orthodontics, reporting of RCTs before the CONSORT statement in 1996 was often insufficient to allow readers to assess the quality of trials (Harrison, 2003).

In a further study, Flint and Harrison assessed reporting of RCTs in four orthodontic journals at three time points (1995/1996 pre-CONSORT, 2000/2001 post-CONSORT and 2005/2006 post revised CONSORT) on the basis of the checklist developed from the CONSORT statement. They found the quality of reporting RCTs had improved over time, but reporting of randomization, allocation concealment and blinding remained inadequate (Flint and Harrison, 2010).

The aim of this study was to provide an update as to whether authors in the orthodontic field of research currently report RCTs adequately as defined by the CONSORT statement checklist.

Materials and Methods

Identification of clinical trials

The title and abstract of all published articles between January 2008 and June 2012 in the American Journal of Orthodontics and Dentofacial Orthopedics (AJO-DO), Journal of Orthodontics (JO), the Angle Orthodontist (AO) and the European Journal of Orthodontics (EJO) were reviewed by one of the authors [first examiner (FA)]. All articles that reported randomized or controlled clinical trials were identified. Identification of the clinical trials was through searching the title and the abstract for the keywords 'Trial', 'Randomized' or 'Assigned' and then retrieving full text for all articles that include one or more of these terms.

Assessment of the trial reporting

The CONSORT 37 item-checklist was used to score the reports (Figure 1). Each item was scored either as 'Yes' if present, 'No' if absent or 'Not applicable' (NA). An item was scored as NA if the design of the study made it impossible to include. The total score for each trial was calculated and converted to a percentage using the equation: total score=(total number of 'Yes'/[37−total number of 'NA' items]) × 100.

Additional data collected

Information related to the following characteristics was also recorded for each article:

- number of authors;
- continent and country of first author;
- clinical setting of the trial.

Reliability

A 10% random sample of the papers was scored by a second examiner (DB) to assess inter-examiner reliability of the CONSORT score. Another 10% random sample of the papers was scored a second time by the first examiner 3 months after initial data collection was completed to test intra-examiner reliability.

Results

One hundred and fifty-one (4.6%) clinical trial reports were identified out of 3335 articles reviewed in the four journals from January 2008 to June 2012 (Table 1). Mean CONSORT score for all the trial reports was 51.7%. The scores ranged from 73.6% for the JO to 44.5% for the AO (Table 1). Mean CONSORT score by year of publication increased from 47.8% in 2008 to 56.3% in 2012 (Table 2). Twelve (7.9%) out of the 151 papers satisfactorily reported all the five items related to the method of randomization. Of the remaining 139 articles, reporting of randomization was inadequate in 54 reports (35.8%) and 85 reports (56.3%) did not give details of randomization methods (Table 1).

In 93% of reports, the first author worked in an academic institution and 50% of trials were reported by four or five authors (Table 3). More than half of publications were from Europe (54.3%) (Table 3) and Turkey contributed most (18.5%) followed by the USA (15.9%) and the UK (11.9%). Eighty-four per cent of the trials were set in university clinics, 9.3% were in private practice and 6.6% were in hospital or public clinics.

Reliability

Bland and Altman plots (Figure 2 a,b) showed no systematic error in the CONSORT checklist scoring and the random error was deemed to be within acceptable limits for both inter-examiner and intra-examiner reliability as the difference in scoring a trial was small.

Discussion

This retrospective study has looked into the quality of reporting of orthodontic RCTs that contribute to systematic reviews and drive evidence-based dentistry. The number of RCTs in the orthodontic literature is small, and so it is important they are planned, conducted and reported to a high standard. Indeed, they account for only 5.26% of articles published in the AJO-DO (Pandis *et al.*, 2011), which is consistent with the findings of this study.

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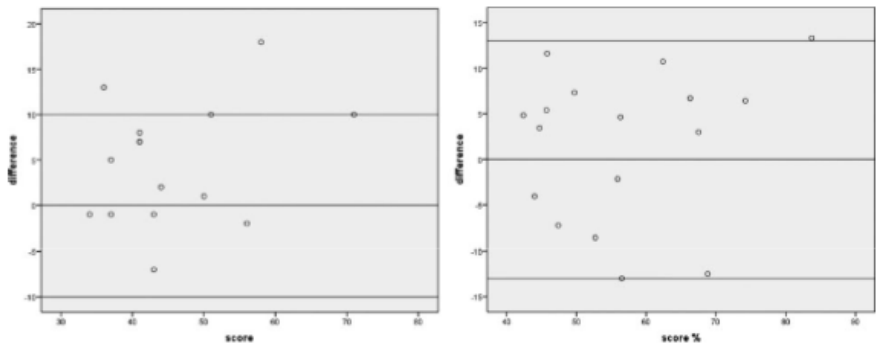

Figure 2 (a) Bland–Altman plot for intra-examiner reliability test (b) Bland–Altman plot for inter-examiner reliability test

In a Thomson Reuter global research report, the number of published research articles from Turkey increased from 5000 reports in 2000 to 22,000 reports in 2009 (Adam *et al.*, 2011).

One limitation of this study relates to the sample size, which prevented statistical comparison between journals. Another limitation of this study may arise from the fact that scoring certain items of the CONSORT checklist has a degree of subjectivity. Inter and intra examiner reliability tests indicate the effects of this subjectivity were limited.

Conducting a RCT requires significant resource and everyday clinical practice depends on their outcomes. Therefore reporting the clinical trial to a high standard to allow readers to make a valid judgement on the risk of bias and quality is as important as designing and conducting them correctly. We support the conclusion of other researchers (Turpin, 2005; Flint and Harrison, 2010; Koletsi *et al.*, 2012a; Seehra *et al.*, 2013) that it is the duty of researchers, journals editors and funding bodies to ensure the continued improvement in the standard of reporting of RCTs.

Conclusion

- Clinical trial reports represented less than 5% of articles in the four main orthodontic journals between 2008 and 2012.
- CONSORT mean score ranged from 44.5 to 73.6% between journals.
- CONSORT mean score increased through the period of investigation.

Disclaimer Statements

Contributors Fahad Alharbi and David Bearn designed the study and agreed the protocol. Fahad Alharbi collected all the data and David Bearn acted as the second data collector on a selected sub-sample. Fahad Alharbi and David Bearn wrote the manuscript. David Bearn is the guarantor.

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Ethics approval Ethical approval not required.

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APPENDIX 2. Search strategy for miniscrews failure rate systematic review.

Databases of published trials	Search strategy used
MEDLINE searched via PubMed (February 28, 2011-September 14, 2015) www.ncbi.nlm.nih.gov/sites/entrez/	((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh]) OR ("clinical trial"[tw]) OR ((singl*[tw] OR doubl*[tw] OR trebl*[tw] OR tripl*[tw]) AND (mask*[tw] OR blind*[tw])) OR (placebos[mh] OR placebo*[tw] OR random*[tw] OR research design[mh:noexp] OR comparative study OR evaluation studies OR follow-up studies[mh] OR prospective studies[mh] OR control*[tw] OR prospectiv*[tw] OR volunteer*[tw])) AND (((orthodont*) OR (tooth movement*) OR (malocclusion*)) AND ((implant*) OR (miniscrew*) OR (mini screw*) OR (mini implant*) OR (miniscrew implant*) OR (mini screw implant*) OR (microscrew*) OR (micro screw*) OR (microimplant*) OR (micro implant*) OR (microscrew implant*) OR (micro screw implant*) OR (osseointegrat*) OR (absolute anchorage) OR (skeletal anchorage) OR (stationary anchorage) OR (infinite anchorage) OR (TADs) OR (temporary anchorage) OR (temporary absolute anchorage) OR (temporary skeletal anchorage) OR (temporary stationary anchorage)))
Cochrane Database of Systematic Reviews searched via The Cochrane Library (February 28, 2011-September 14, 2015) www.thecochranelibrary.com	(orthodont* OR tooth movement* OR malocclusion*) and ((implant*) OR (miniscrew*) OR (mini screw*) OR (mini implant*) OR (miniscrew implant*) OR (mini screw implant*) OR (microscrew*) OR (micro screw*) OR (microimplant*) OR (microimplant*) OR (microscrew implant*) OR (micro screw implant*) OR (osseointegrat*) OR (absolute anchorage) OR (skeletal anchorage) OR (stationary anchorage) OR (infinite anchorage) OR (TADs) OR (temporary anchorage) OR (temporary absolute anchorage) OR (temporary skeletal anchorage) OR (temporary stationary anchorage))
Scopus searched (2011- 2015) www.scopus.com	(ALL(orthodont* OR malocclusion* OR "tooth movement*") AND ALL(implant* OR miniscrew* OR "mini screw*" OR "mini implant*" OR "miniscrew implant*" OR "mini screw implant*" OR microscrew* OR "micro screw*"OR microimplant* OR "micro implant*" OR "tads*" OR microscrew implant* OR "micro screw implant*" OR osseointegrat* OR anchorag)) AND (LIMIT-TO(DOCTYPE, "ar")) AND (LIMIT-TO(SUBJAREA, "DENT") OR LIMIT-TO(SUBJAREA, "MULT"))
Ovid database searched (2011-2015) http://ovidsp.ovid.com/autologin.html	(((orthodont*) OR (tooth movement*) OR (malocclusion*)) AND ((implant*) OR (miniscrew*) OR (mini screw*) OR (mini implant*) OR (miniscrew implant*) OR (mini screw implant*) OR (microscrew*) OR (micro screw*) OR (microimplant*) OR (micro implant*) OR (microscrew implant*) OR (micro screw implant*) OR (osseointegrat*) OR (absolute anchorage) OR (skeletal anchorage) OR (stationary anchorage) OR (infinite anchorage) OR (temporary anchorage) OR (temporary absolute anchorage) OR (temporary skeletal anchorage) OR (TADs) OR (temporary stationary anchorage)))

Appendix 3. Search strategy for anchorage effectiveness of miniscrews systematic review.

Databases of published trials	Search strategy used
MEDLINE searched via PubMed (1950-March 15, 2016) www.ncbi.nlm.nih.gov/sites/entrez/	((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh]) OR ("clinical trial"[tw]) OR ((singl*[tw] OR doubl*[tw] OR trebl*[tw] OR tripl*[tw]) AND (mask*[tw] OR blind*[tw])) OR (placebos[mh] OR placebo*[tw] OR random*[tw] OR research design[mh:noexp] OR comparative study OR evaluation studies OR follow-up studies[mh] OR prospective studies[mh] OR control*[tw] OR prospectiv*[tw] OR volunteer*[tw])) AND (((orthodont*) OR (tooth movement*) OR (malocclusion*)) AND ((implant*) OR (miniscrew*) OR (mini screw*) OR (mini implant*) OR (miniscrew implant*) OR (mini screw implant*) OR (microscrew*) OR (micro screw*) OR (microimplant*) OR (micro implant*) OR (microscrew implant*) OR (micro screw implant*) OR (osseointegrat*) OR (absolute anchorage) OR (skeletal anchorage) OR (stationary anchorage) OR (infinite anchorage) OR (temporary anchorage) OR (temporary absolute anchorage) OR (temporary skeletal anchorage) OR (TADs) OR (headgear) OR (headbrace) OR (facebow) OR (retraction headgear) OR (palatal bar) OR (transpalatal arch) OR (transpalatal arch) OR (Goshgarian bar) OR (lingual bar)))
Cochrane Database of Systematic Reviews searched via The Cochrane Library (1974- March 15, 2016) www.thecochranelibrary.com	(orthodont* OR tooth movement* OR malocclusion*) and ((implant*) OR (miniscrew*) OR (mini screw*) OR (mini implant*) OR (miniscrew implant*) OR (mini screw implant*) OR (microscrew*) OR (micro screw*) OR (microimplant*) OR (microimplant*) OR (microscrew implant*) OR (micro screw implant*) OR (osseointegrat*) OR (absolute anchorage) OR (skeletal anchorage) OR (stationary anchorage) OR (infinite anchorage) OR (temporary anchorage) OR (temporary absolute anchorage) OR (temporary skeletal anchorage) OR (TADs) OR (temporary stationary anchorage) OR (headgear) OR (headbrace) OR (facebow) OR (retraction headgear) OR (palatal bar) OR (transpalatal arch) OR (transpalatal arch) OR (Goshgarian bar) OR (lingual bar))
Scopus searched on March 15, 2016 www.scopus.com	(ALL(orthodont* OR malocclusion* OR "tooth movement*") AND ALL(implant* OR miniscrew* OR "mini screw*" OR "mini implant*" OR "miniscrew implant*" OR "mini screw implant*" OR microscrew* OR "micro screw*"OR microimplant* OR "micro implant*" OR microscrew implant* OR "micro screw implant*" OR "tads*" OR osseointegrat* OR anchorag) OR (headgear*) OR (facebow*) OR (retraction headgear*) OR (palatal bar*) OR (transpalatal arch*) OR (Goshgarian bar*) OR (lingual bar*)) AND (LIMIT-TO(DOCTYPE,"ar")) AND (LIMIT-TO(SUBJAREA,"DENT") OR LIMIT-TO(SUBJAREA,"MULT")) AND (

	EXCLUDE(EXACTKEYWORD,"Animal") OR EXCLUDE(EXACTKEYWORD,"Animals") OR EXCLUDE(EXACTKEYWORD,"Histology")) AND (EXCLUDE(EXACTKEYWORD,"Case report")) AND (LIMIT-TO(LANGUAGE,"English"))
Ovid database searched on March 15, 2016 http://ovidsp.ovid.com/autologin.html	(((orthodont*) OR (tooth movement*) OR (malocclusion*)) AND ((implant*) OR (miniscrew*) OR (mini screw*) OR (mini implant*) OR (miniscrew implant*) OR (mini screw implant*) OR (microscrew*) OR (micro screw*) OR (microimplant*) OR (micro implant*) OR (microscrew implant*) OR (micro screw implant*) OR (osseointegrat*) OR (headgear*) OR (facebow*) OR (retraction headgear*) OR (palatal bar*) OR (transpalatal arch*) OR (Goshgarian bar*) OR (lingual bar*) OR (absolute anchorage) OR (skeletal anchorage) OR (stationary anchorage) OR (infinite anchorage) OR (temporary anchorage) OR (temporary absolute anchorage) OR (temporary skeletal anchorage) OR (temporary stationary anchorage)))

Appendix 4. The patient information form

PARTICIPANT INFORMATION LEAFLET
The HAP STUDY

We are asking if you would take part in a project to find the answer to the question: 'What is the best device to support the back teeth during brace treatment?'

Before you decide if you want to join the project it is important to understand why the project is being done and what it will mean for you. . Your orthodontists will go through this information leaflet with you and answer any questions you may have. Please feel free to talk about it with your family, friends, or dentist if you want to.

Why are we doing this project?
Young people who come to the orthodontist with crowded or crooked teeth often need extra support to the back teeth while they are wearing their braces. In this project we will compare three methods used for supporting the back teeth. These three methods are:

1. a mini-screw or 'gum stud' which is placed inside your mouth on the gums
2. a palatal arch, which is a metal bar across the roof of your mouth.
3. headgear or 'head brace', which goes around the back of your head.

This project will help us to find out which of these is best.

Why have I been invited to take part?
You have been invited to join our project because you have crooked teeth and will need extra support to your back teeth when your brace is fitted. We will need 45 young people just like you to join the project.

Do I have to take part?
No, you don't have to take part. It's up to you. If you do, your orthodontist will ask you to sign a form giving your permission. You will be given a copy to keep. You are free to stop taking part at any time without giving a reason. If you decide to stop, this will not affect your brace treatment.

What will happen to me if I take part?
If you decide to take part, you will be 'randomly allocated' by a computer program to one of the three methods of supporting your brace. This is like throwing a dice to find out which one you will get. You will be involved in the project until your braces come off. We will follow your treatment carefully and record how you get on and what your teeth are like at the end.

What will I be asked to do?
You will not be asked to make extra visits to your orthodontist.
A mould of your upper teeth will be taken when the first brace is fitted, after six months of treatment and again when the supporting device is finished. At these last two visits the small bands that wrap around the back teeth that help support the brace will be removed prior to the mould been taken. These bands will then be refitted using tooth glue. At this point a slight taste of glue may be present. This process will only take about five to ten minutes and will be done during one of your normal visits.

You will also be asked to complete a simple questionnaire at the beginning of your treatment, after six months of brace treatment and when your braces come off. The total time for brace treatment is normally between 18-24 months.

What are the advantages and disadvantages of the three methods?
The first device is called Headgear. This is the most visible method, but you will mostly wear it during the night. Many orthodontists feel this is the strongest method of support and as such is routinely used. It is common to feel slight toothache for the first 3-5 days after the headgear if worn. If necessary, painkillers such as the ones you would normally take for a headache may help (please read the instructions on the packet for correct dose). More uncommon risks are allergic reaction on the cheeks and, very rarely eye injuries have been reported when the safety instructions have not been followed.

The second device used is a palatal arch; which is a wire that goes across the roof of your mouth. This may be uncomfortable at first. If necessary, painkillers can be taken as discussed above. This method is not thought to be as strong a method of support as headgear by some orthodontists The common risks of this are initial discomfort and some problems eating if your food is not cut into bite size pieces. Less commonly ulceration on the tongue or feelings of the arch digging in to the roof of the mouth can occur.

Mini-screws or gum studs are the newest method of support. To fit the studs the gum is numbed; using local anaesthetic. The gum stud is gently inserted into the bone. The mini-screw insertion is not painful, an odd pressure sensation may be felt when the screw is inserted. It is the smallest and least visible method of supporting your back teeth. The common risks of mini-screws are loosening of the screw and discomfort for the first 24 hours after the anaesthetic wears off. As with the other devices painkillers can be taken if required (see headgear). Very rarely the screws may break or the screw can hit a tooth root during placement, but it should heal with no problems.

What are the possible benefits of taking part?
We cannot promise that the project will help you but the information we get should help orthodontists choose the best method for young people having braces in the future.

Will anyone else know I'm doing this?
We will keep your information in confidence. This means we will only tell those who have a need or a right to know, this will include your general dentist, some of the staff at the hospital and the research staff running this project.

What will happen to the information collected for the study?
Your information will have your name and address removed. They will be given a code number and transferred to the project team at the University of Dundee where they will be measured. This code will ensure that nobody there can identify you.

Who is organising and funding the research?
The research is being run in a number of different hospitals but the project team at the University of Dundee are in charge overall. The British Orthodontic Society Foundation has provided money to support the project.

Who has reviewed the study?
This study has been reviewed by a NHS Research Ethics Committee, which has the responsibility for scrutinising proposals for medical research in humans. In this case, the reviewing Committee was the Tayside Committee on Medical Research Ethics who have raised no objections from the point of view of medical ethics.

Thank you for reading this Information Leaflet and considering taking part in this study. Please ask any questions if you need to.

Contact details:
For further information about the project you can ask:

Local PI Information

Or contact:
Prof. David Bearn
Professor of Orthodontics
Dundee Dental School
Park Place
Dundee
DD1 4HN

E-mail: d.bearn@dundee.ac.uk

Tel 01382 635978

Appendix 5. Study consent from

Centre Number: ☐ Patient Identification number: ☐

CONSENT FORM

Title of Project: Are mini-screws effective at providing orthodontic anchorage? The HAP Study

Name of Researcher / Orthodontist who explained the project to you:

Please answer the following questions:

		INITIALS
Have you read (or had read to you) about this project	Yes ☐ No ☐	☐
Have you read (or had read to you) about this project?	Yes ☐ No ☐	☐
Has somebody explained this project to you?	Yes ☐ No ☐	☐
Do you understand what this project is about?	Yes ☐ No ☐	☐
Have you asked all the questions you want?	Yes ☐ No ☐	☐
Have you had your questions answered in a way you understand?	Yes ☐ No ☐	☐
Do you understand it's OK to stop taking part at any time?	Yes ☐ No ☐	☐
Are you happy to take part?	Yes ☐ No ☐	☐

If <u>any</u> answers are 'no' or you don't want to take part, don't sign your name!

If you <u>do</u> want to take part, please write your name below:

Your name:_____

Date: _____

The Orthodontist who explained this project to you will sign here:

Sign: _____

Date: _____

Centre Number: | | Patient Identification Number: | |

Parent/legal guardian to read and initial box:

I confirm that I have read and understand the information leaflet entitled; **What is the most effective method for providing orthotic anchorage? A Randomised Clinical Trial of; Headgear, AbsoAnchor mini-screws and Palatal arch (HAP Study).leaflet Version 3 dated 9th September 2011**for the above study on behalf of my son/daughter. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

I understand that my child's participation is voluntary and that he/she is free to withdraw at any time without giving any reason, without his/her medical care or legal rights being affected. ☐

I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from the University of Dundee, from regulatory authorities or from the NHS Trust, where it is relevant to my child taking part in this research. I give permission for these individuals to have access to my child's records. ☐

I agree to my child's GDP being informed of my child's participation in the study. ☐

I agree to my child taking part in this study. ☐

Name:	
Relation to patient:	
Date:	
Signature:	

:

Name of person taking consent:	
Date:	
Signature:	

When completed, copy for patient, copy for master file, original to be kept in medical notes.

Appendix 6. Before treatment questionnaire

Treatment Questionnaire (Before)

Study Number _____

These are some of the reasons why people want nicer teeth. Please draw a ring round **one** of the numbers on each line.

	Not a reason			**Very much a reason**
To make my smile nicer	1	2	3	4
To help me chew food better	1	2	3	4
To make my family happy	1	2	3	4
To help me with my schoolwork	1	2	3	4
To make my teeth look nicer	1	2	3	4
To help my breathing	1	2	3	4
To feel more confident	1	2	3	4
To help my top and bottom teeth fit together	1	2	3	4
To help me speak more clearly	1	2	3	4
To make my face look better	1	2	3	4
To make me feel better about myself	1	2	3	4
To keep my gums healthy	1	2	3	4
To make me healthier	1	2	3	4
To keep me from losing teeth in the future	1	2	3	4
To help me make friends	1	2	3	4
To keep my jaw joints healthy	1	2	3	4
To help my front teeth fit together	1	2	3	4
To make me look better	1	2	3	4
To make me feel better about going out	1	2	3	4
To help keep my jaw joint from clicking	1	2	3	4
To help my back teeth fit together	1	2	3	4
To make it easier to get on with people	1	2	3	4
To make it easier to bite into food	1	2	3	4

Please tell us on the other side of the page if there are any other reasons why you want nicer teeth

The HAP Study – Before Treatment Questionnaire Version 2 (28th May 2010)

Appendix 7. After treatment questionnaire

Treatment Questionnaire (After)

Study Number _____

We would like to know how things have changed for you because of your treatment. Please draw a ring round one of the numbers on each line which is nearest to how you feel.

	No better	A little better	Much better	Very much better
It has made it easier to chew my food	1	2	3	4
It has made my family happier	1	2	3	4
It has helped me with my schoolwork	1	2	3	4
It has made my teeth look nicer	1	2	3	4
It has helped my breathing	1	2	3	4
It has made me more confident	1	2	3	4
It has helped my top and bottom teeth fit together	1	2	3	4
It has helped me speak more clearly	1	2	3	4
It has made my face look better	1	2	3	4
It has made me feel better about myself	1	2	3	4
It has made my gums healthier	1	2	3	4
It has made me healthier	1	2	3	4
It will stop me losing teeth in the future	1	2	3	4
It is easier to make friends	1	2	3	4
It has helped to keep my jaw joints healthy	1	2	3	4
It has helped my front teeth fit together	1	2	3	4
It has made me look better	1	2	3	4
It has made me feel better about going out	1	2	3	4
It keeps my jaw joint from clicking	1	2	3	4
It has helped my back teeth fit together	1	2	3	4
It has made it easier to get on with people	1	2	3	4
It has made it easier to bite into food	1	2	3	4

If there have been any other changes because of your treatment please tell us about them on the other side of the paper.

The HAP Study – After Treatment Questionnaire Version 2 (28th May 2010)

Appendix 8. Smile better questionnaire

Smiles Better

A few questions about you and your brace

A Few Questions About You And Your Brace

We would like to know how you feel about wearing your brace. By answering these questions, YOU can help to make wearing a brace better for people in the future.

Please circle the answer, which is nearest to how you feel, like this :

If you think wearing a brace has improved your smile put a ring around *improved*
or
How often do you play sport Not at all A little A lot

*Please tell us about how you feel **NOW**, not about when your brace was new.*

---

1. How much have the following things changed because of wearing your brace?

Speech	Improved	Same	Slightly worse	Much worse
Eating	Improved	Same	Slightly worse	Much worse
Drinking	Improved	Same	Slightly worse	Much worse
Sleeping	Improved	Same	Slightly worse	Much worse
Appearance	Improved	Same	Slightly worse	Much worse
I am teased	Less	Same	Slightly more	Much more

2. Now you are wearing a brace, how have the following affected you?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot
Dribbling	Not at all	A little	A lot
Keeping the brace clean is a nuisance	Not at all	A little	A lot

We would like to know if wearing a brace can affect other things in your life.

SCHOOLWORK

3a. How have the following things associated with wearing a brace affected your schoolwork?

For example, if you think your schoolwork is better you would put a ring around

improved

How have any changes in your speech affected your schoolwork ?	Improved	Same	Worse	Much Worse
How have any changes in your eating affected your schoolwork ?	Improved	Same	Worse	Much Worse
How have any changes in how you drink affected your schoolwork ?	Improved	Same	Worse	Much Worse
How have any changes in your sleep patterns affected your schoolwork ?	Improved	Same	Worse	Much Worse
How have any changes in your appearance affected your schoolwork ?	Improved	Same	Worse	Much Worse
If you have experienced teasing how has it affected your schoolwork ?	Improved	Same	Worse	Much Worse

3b. How have your experiences of the following affected your schoolwork?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot
Dribbling	Not at all	A little	A lot
Keeping the brace clean	Not at all	A little	A lot

GETTING ON WITH FRIENDS

4a. How have the following things associated with wearing your brace affected your friendships?

For example, if you think it is easier to get on with your friends because of the way your brace has changed your smile, you would put a ring around (improved)

How have any changes in your speech affected your friendships ?	Improved	Same	Worse	Much Worse
How have any changes in your eating affected your friendships ?	Improved	Same	Worse	Much Worse
How have any changes in how you drink affected your friendships?	Improved	Same	Worse	Much Worse
How have any changes in your sleep patterns affected your friendships ?	Improved	Same	Worse	Much Worse
How have any changes in your appearance affected your friendships?	Improved	Same	Worse	Much Worse
If you have experienced teasing how has it affected your friendships ?	Improved	Same	Worse	Much Worse

4b. How have your experiences of the following affected the way in which you get on with your friends?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot
Dribbling	Not at all	A little	A lot
Keeping the brace clean	Not at all	A little	A lot

FAMILY RELATIONSHIPS

5a. How have the following things associated with wearing a brace affected how you get on with your family?

For example, if you think you argued a lot more with your parents because of your brace, you would put a ring around (much worse)

How have any changes in your speech affected your relationship with your family?	Improved	Same	Worse	Much Worse
How have any changes in your eating affected your relationship with your family?	Improved	Same	Worse	Much Worse
How have any changes in how you drink affected your relationship with your family?	Improved	Same	Worse	Much Worse
How have any changes in your sleep patterns affected your relationship with your family?	Improved	Same	Worse	Much Worse
How have any changes in your appearance affected your relationship with your family?	Improved	Same	Worse	Much Worse
If you have experienced teasing how has it affected your relationship with your family?	Improved	Same	Worse	Much Worse

5b. How have your experiences of the following affected your relationship with your family?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot
Dribbling	Not at all	A little	A lot
Keeping the brace clean	Not at all	A little	A lot

HOBBIES / INTERESTS

6. If you feel that wearing a brace has had any effect on your hobbies please tick the appropriate box.

For example:

If you feel that wearing a brace has meant that you get the lead roles in the school play you would tick the **I enjoy doing more** *box beside* **drama**

Activity	I enjoy doing more…….	No different	I do less…….
Music			
Sport			
Drama			
Singing			
Going to clubs eg Scouts or guides			

If you think wearing a brace has affected other hobbies or interests please write them in the activity column and say in what way by ticking the appropriate boxes.

TOOTH MOVEMENT

Now that you are wearing a brace do you feel that your teeth are moving?	Not at all	A little
A lot		
Is it important to you whether or not your teeth are moving?	Not at all	A little
A lot		

YOUR EXPERIENCE OF WEARING A BRACE

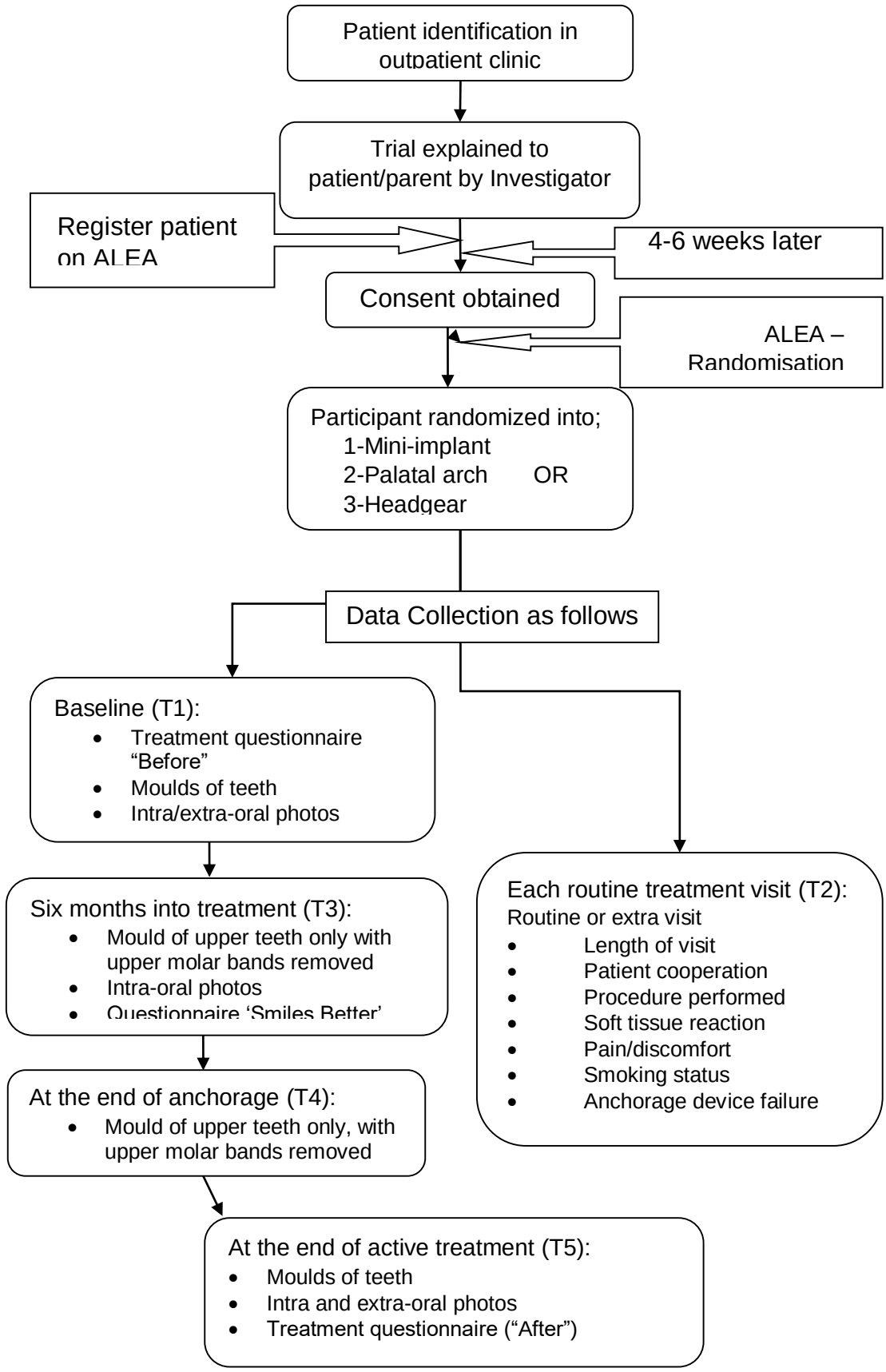
Is wearing a brace what you expected?		Yes	No	Not sure
Have you had any extra visits to the hospital because your brace has broken?	Yes	No		
If you have had to make extra visits because your brace has broken, has this bothered you?		Not at all	A little	A lot

YOUR ADVICE TO OTHER PATIENTS

Based upon **YOUR** experience of wearing a brace, what would **YOU** say to someone who was about to have a brace fitted?

Appendix 10. Sample of study new letter.

Appendix 9. Flowchart of the trial



Appendix 10. Treatment progress

Visit	Date	Routine (R) visit OR Extra (E) R/E	Smoking status Y/N	Soft tissue reaction* Y/N	pain/ discomfort + Y/N	Procedure (Please also include : • reason for extra visit if applicable • missed or cancelled appointments since last visit	Length of visit (minutes)	Has anchorage device failed? Y/N
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

Appendix 11. Newsletter February 2013

HAP STUDY Investigator Newsletter

February 2013

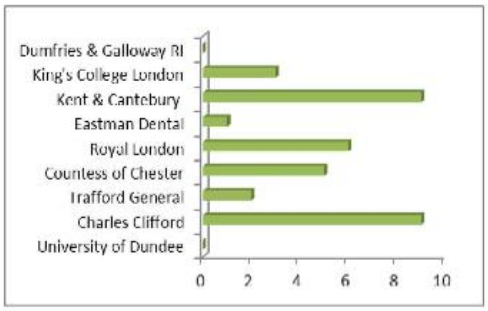


Figure 1. The number of randomised patients per site

Dr Roberta Littleford
HAP Study Trial Co-ordinator
Ninewells Hospital & Medical School
TASC , Residency Block, Level 3
George Pirie Way, Dundee, UK, DD1 9SY
Telephone: 01382 383242/M: 07931442469
r.littleford@dundee.ac.uk

WELCOME TO A NEW INVESTIGATOR

We would like to welcome Mr Satvinder Bhopal, Consultant Orthodontist based at the Dumfries and Galloway Royal Infirmary. Satvinder will commence recruitment in the next few weeks after settling into his new post. We wish him luck and great recruitment!

RECRUITMENT

As ever, recruitment continues to be below the projected numbers. In response to a progress report submitted to our funder, BOS, they have commented on recruitment by having;

continuing concerns about the rate of recruitment to this study.

Currently we have 35 patients randomized, although at the last monitoring visit it appeared that 5 patients may have been lost to follow-up. This figure will be confirmed at the next monitoring visit (see p2). Forty-seven patients have been registered and 12 have given a reason for not consenting to take part in the study.

BOS have requested another report and a strategy plan to increase recruitment. Could you please indicate if you will be able to recruit a few more patient before the scheduled end of recruitment date of July 2013. **1 each would just about do it!**

HAP STUDY Investigator Newsletter

Monitoring Visits

Table 2 below outlines the proposed dates for my forthcoming visits; 3rd week in May 2013. Please indicate your availability by email. If you are unable to be there in person please arrange a delegate to assist with the documentation check.

Table 3 outlines the items that will be required to check and remove for data entry.

There are only two rules for being successful. One, figure out exactly what you want to do, and two, do it.
- Mario Cuomo

INVESTIGATOR(S)	LOCATION	DATE /TIME May 2013
David Bearn	Dundee	TBC
Satvinder Bhopal	Dumfries & Galloway	TBC
Philip Benson	Charles Clifford	Mon 13th (AM)
Stephen Chadwick	Countess of Chester	Tues 14th (AM)
Alison Johnson/ Susi Caldwell	Trafford	Wed 15th (AM)
Gavin Mack	King's College	Thurs 16th (AM)
Shirley Cox/ Padhraig Fleming	Barts & The London	Fri 17th (AM)
Sam Hodges	Eastman	Fri 17th (PM)
Andrew DiBiase	Kent & Canterbury	Mon 20th (AM)

Table 2. Proposed Visit Dates

ITEMS REQUIRED	CHECKS/COLLECTION
Informed Consent	100% check
Participant Booklets	100% check (collect if completed)
Medical/Dental Records	Source Document Review
Questionnaires	Collect for Data Entry
Models	Collect for 3D analysis

Table 3. Requirements for monitoring visits.

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Angela Stroud
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Sent: 14 July 2016 20:36
To: Angela Stroud <astroud@georgewarman.co.uk>
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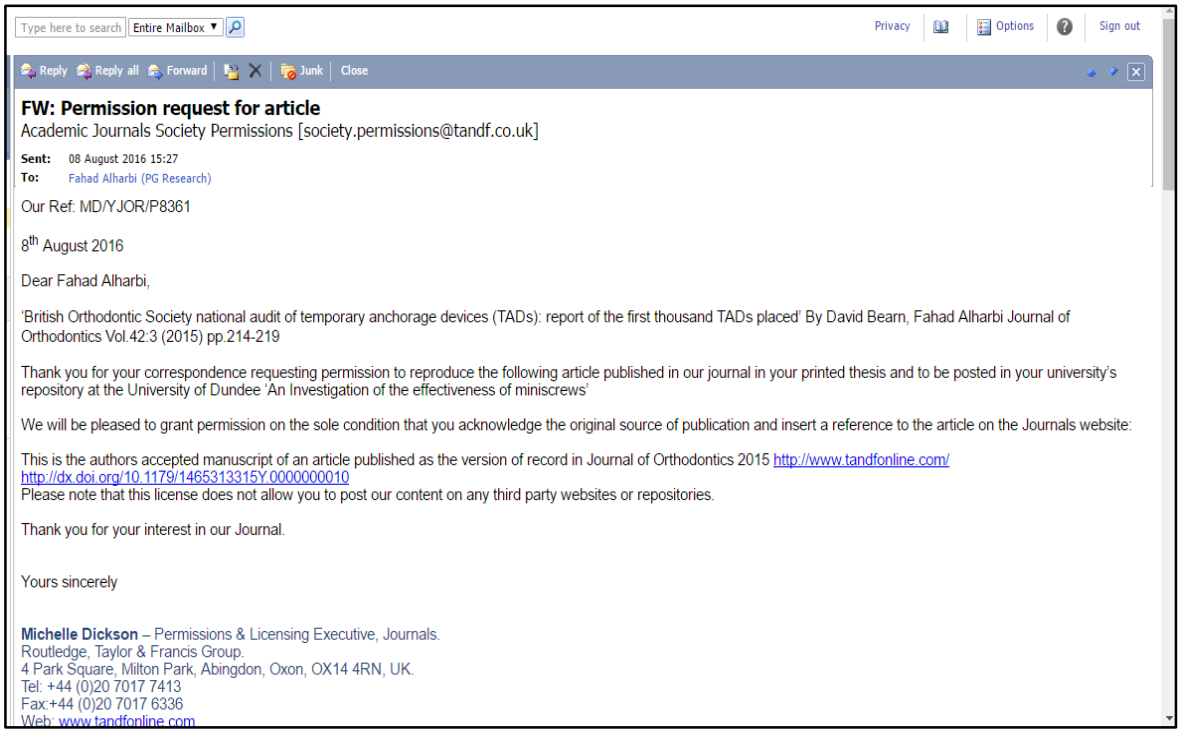

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